Exhibit 1

(TO PLAINTIFF'S ATTORNEY: PLEASE CIRCLE TYPE OF ACTION INVOLVED: TORT - MOTOR VEHICLE TORT - CONTRACT - EQUITABLE RELIEF - (OTHER))

COMMONWEALTH OF MASSACHUSETTS

NORFOLK, ss.

SUPERIOR COURT
CIVIL ACTION

NO. 19 0400

Town of Randolph, *Plaintiff(s)*

v.

CVS Health Corporation, et al., *Defendant(s)*

SUMMONS

To the above-named Defendant:

You are hereby summoned and required to serve upon Judith S. Scolnick plaintiff's attorney, whose address is 230 Park Ave, 17th Fl., New York, NY 10169 an answer to the complaint which is herewith served upon you, within 20 days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You are also required to file your answer to the complaint in the office of the Clerk of this court at Dedham either before service upon the plaintiff's attorney or within a reasonable time thereafter.

Unless otherwise provided by Rule 13(a), your answer must state as a counterclaim any claim which you may have against the plaintiff which arises out of the transaction or occurrence that is the subject matter of the plaintiff's claim or you will thereafter be barred from making such claim in any other action.

WITNESS, JUDITH FABRICANT, Esquire, at ..... the .....

day of ....., in the year of our Lord two thousand and .....

Walter D. Duffy *Clerk.*

NOTES:
1. This summons is issued pursuant to Rules 4 of the Massachusetts Rules of Civil Procedure.
2. When more than one defendant is involved, the names of all such defendants should appear in the caption. If a separate summons is used for each such defendant, each should be addressed to the particular defendant.

F-33

PROOF OF SERVICE OF PROCESS

I hereby certify and return that on ....., 20 , I served a copy of the within summons, together with a copy of the complaint in this action, upon the within-named defendant, in the following manner (See Mass. R. Civ. P. 4 (d) (1-5):

.....

.....

.....

Dated: , 20 .....

N. B. TO PROCESS SERVER:-
PLEASE PLACE DATE YOU MAKE SERVICE ON DEFENDANT IN THIS BOX ON THE ORIGINAL AND ON COPY SERVED ON DEFENDANT.

, 20

COMMONWEALTH OF MASSACHUSETTS

NORFOLK, ss.

SUPERIOR COURT
CIVIL ACTION

NO. 19-0400

Town of Randolph, Plaintiff

v.

CVS Health Corporation et al., Defendant

SUMMONS

(Mass. R. Civ. P.4)

COMMONWEALTH OF MASSACHUSETTS

Norfolk, ss.

Superior Court Department
Civil Action No. _____

TOWN OF RANDOLPH,

Plaintiff,

v.

PURDUE PHARMA L.P. d/b/a PURDUE PHARMA (DELAWARE) LIMITED PARTNERSHIP; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; COLLEGIUM PHARMACEUTICAL, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; and INSYS THERAPEUTICS, INC.,

Manufacturer Defendants,

- and -

MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCE BERGEN DRUG CORPORATION; CVS HEALTH CORPORATION; CVS PHARMACY, INC.; RITE AID CORPORATION; RITE AID OF MASSACHUSETTS, INC.; WALGREENS BOOTS ALLIANCE, INC.; WALGREEN EASTERN CO., INC.; WALGREENS MAIL SERVICE, L.L.C.; WALGREENS OF MASSACHUSETTS, L.L.C.; WALGREENS SPECIALTY PHARMACY, L.L.C.; WALMART, INC.; WAL-MART.COM USA, L.L.C.; WAL-MART STORES EAST, INC.; and WAL-MART STORES EAST, L.P.,

Distributor Defendants,

- and -

19 0400

2019 MAR 27 PM 3:22
CLERK OF THE COURTS
NORFOLK COUNTY

JOHN KAPOOR, RICHARD SACKLER, THERESA SACKLER, KATHE SACKLER, JONATHAN SACKLER, MORTIMER DA. SACKLER, BEVERLY SACKLER, DAVID SACKLER, and ILENE SACKLER LEFCOURT,

Individual Defendants.

COMPLAINT AND JURY TRIAL DEMAND

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COMPLAINT

Plaintiff Town of Randolph alleges as follows:

I. PRELIMINARY STATEMENT

1. Like many communities in the United States, the Town of Randolph, Massachusetts (referred to herein as "Plaintiff," "Randolph," "Town," or "Town of Randolph"), are currently experiencing a stark increase in the number of residents who have become addicted to prescription opioids and heroin, and a stark increase in opioid overdoses. Prescription opioids are now known to be the "gateway" drug to heroin; approximately 80% of current heroin users got their start with prescription opioids.[1] Unlike any other epidemic, the opioid epidemic is not natural, nor typical, but largely man-made. It has been created, fueled, and continues to expand by the persistent unlawful conduct of the defendant pharmaceutical manufacturers ("Manufacturer Defendants") and pharmaceutical wholesale distributors ("Distributor Defendants").

2. A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers. Drug manufacturers have a legal duty to ensure that their products are accompanied by full and accurate instructions and warnings to guide prescribing doctors and other healthcare providers in making treatment decisions. Pharmaceutical manufacturers have legal duties to tell the truth when marketing their drugs and to ensure that their marketing claims are supported by science and medical evidence. A pharmaceutical distributor of controlled substances has a legal duty to conduct its business lawfully, carefully, and in a manner that does not irresponsibly and unreasonably saturate a community with opioids. Executives of

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[1] *Prescription Opioids and Heroin: Prescription Opioid Use is a Risk Factor for Heroin Use*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use (last updated Jan. 2018).

pharmaceutical companies, such as Individual Defendants (defined below), have a legal obligation to ensure that their company conducts business in a manner compliant with the law that is designed to protect rather than harm patients. Defendants broke these simple rules.

3. Manufacturer Defendants (collectively consisting of Defendants Purdue Pharma L.P. d/b/a Purdue Pharma (Delaware) Limited Partnership; Purdue Pharma Inc.; The Purdue Frederick Company, Inc.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Collegium Pharmaceutical, Inc.; Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals, Inc.; Allergan plc f/k/a Actavis plc; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Watson Laboratories, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Mallinckrodt PLC; Mallinckrodt LLC; and Insys Therapeutics, Inc.) knew that opioids were effective treatments for short-term use, such as post-surgical and trauma-related pain, and for end-of-life care. They also knew, or reasonably should have known, that prescription opioids were addictive and subject to abuse, particularly when used over a prolonged period of time, and should be used, if at all, as a last resort. Defendants[2] also knew, or reasonably should have known, that with prolonged use, the effectiveness of opioids decreases, requiring dosage increases to reduce pain, thereby increasing the risk of significant side effects and addiction. Defendants also knew that there were no clinical trial results in existence that showed that opioids were safe for long-term treatment of chronic pain, although they falsely represented that the safety of such drugs for long-term use had been authoritatively established.

[2] "Defendants" collectively include Manufacturer Defendants, Distributor Defendants (further defined below), and the Individual Defendants.

4. Prior to the mid-1990s, medical orthodoxy rejected the use of opioids as an accepted modality for the long-term treatment for chronic pain. The U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[3]

5. In order to expand their market for opioids and realize blockbuster profits, Manufacturer Defendants needed to create a fundamental change in medical orthodoxy and public perception that would make opioids permissible and even the preferred treatment modality, not just for acute and palliative care, but also for long-term treatment of everyday aches and pains, like lower back pain, arthritis, headaches, and sports injuries.

6. Since the mid-1990s, the Manufacturer Defendants, led by Purdue (defined below), have engaged in a scheme to boost sales for their prescription opioid products by upending medical orthodoxy and popular belief regarding the safety and efficacy of long-term opiate use. Defendants accomplished this reversal by falsely exaggerating the safety of opioid use and, recklessly and negligently, and with wanton disregard for the public health, denying or trivializing the risk of addiction.

7. In furtherance of their scheme, each Manufacturer Defendant expended millions of dollars and used the following unethical and unlawful methods to disseminate misinformation regarding the safety and efficacy of long-term opioid use for pain management treatment, including:

(a) paying off doctors, known as Key Opinion Leaders ("KOLs"), to give speeches and write misleading studies advocating the advantages of prescription opioids

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[3] Janet Woodcock, *FDA/CDER Response to Physicians for Responsible Opioid Prescribing – Partial Petition Approval and Denial*, REGULATIONS.GOV (Sept. 10, 2013), *available at* https://www.regulations.gov/document?D=FDA-2012-P-0818-0793.

and to present deceptive continuing medical education programs ("CMEs") promulgating the message to fellow physicians that opioids were a risk-free and safe treatment modality that was the most effective treatment for most, if not all, types of pain;

(b) promoting the use of opioids for chronic pain through sales representatives, also called "detailers," whose jobs involved visiting individual physicians and their staff in their offices and setting up small group speaker programs. By establishing close relationships with doctors, the sales representatives were able to disseminate their misrepresentations in targeted one-on-one settings that allowed them to address and dispel individual prescribers' reservations about prescribing opioids for chronic pain. Representatives were trained on techniques to build these relationships, with Manufacturer Defendant Actavis (defined below) even rolling out an "Own the Nurse" kit as a "door opener" to time with doctors. The Massachusetts Attorney General produced a document, attached as Exhibit A to its Complaint against Purdue (the "June 12, 2018 Mass AG Complaint"), showing that sales representatives from just one Manufacturing Defendant, Purdue, met with Massachusetts prescribers and pharmacists ***more than 150,000 times*** between May 15, 2007 and December 22, 2017. Using the sales representatives as "foot soldiers" in the misinformation campaign, the Manufacturer Defendants were able to address individual prescribers' concerns about prescribing opioids for chronic pain and push higher doses of the opioids, thereby driving up revenue.

(c) twisting scientific literature; most notably, transforming a five-sentence letter written to the New England Journal of Medicine in 1980 by Doctor Hershel Jick and his graduate assistant, Jane Porter (the "Porter/Jick Letter"), regarding the relative safety of short-term opioid use by patients in a medical setting, into a false assertion (cited more

than 900 times) that long-term opioid use in a non-medical setting has been proven to be "safe" and non-addictive;

(d) infiltrating medical societies and CMEs with the false information that chronic pain could and should be safely treated with prescription opioids;

(e) using non-branded advertisements (that promote opioids generally, rather than any particular brand), which advertisements are not regulated by the FDA, to falsely promise relief from pain with no harmful side-effects from opioids;

(f) providing front groups with tens of millions of dollars and giving them official-sounding names, such as "American Pain Foundation," to disseminate the falsehood that addiction is a very minor and easily handled risk of prescription opioids; and

(g) influencing consumers and the lay public through media, e.g. magazine articles, newspaper stories, TV programs, etc., featuring KOLs and front groups discussing the falsely described advantages of opioids for chronic pain, with the specific intention and effect of recruiting patients to demand opioids from their treating physicians.

8. Defendants' actions are not permitted or excused by the fact that the FDA did not require that their products' labels specifically exclude the use of opioids for chronic pain. Accurate content on a label of a pharmaceutical product is squarely the responsibility of the manufacturer. The FDA's approval of their drugs for narrowly defined applications did not entitle Defendants to misrepresent the risks, benefits, or superiority of opioids. In fact, unlike any other prescription drugs that may have been marketed unlawfully in the past, opioids are highly addictive controlled substances. Thus, Manufacturer Defendants deceptively engaged – and in many instances profoundly harmed – a patient base that by definition was not able, biologically, to turn away from

the drugs. These drugs would never have been prescribed in the first place, but for the Manufacturer Defendants' unlawful scheme.

9. Defendants' causal role is also not broken by the involvement of legitimate doctors writing opioid prescriptions for their patients. Defendants' ubiquitous marketing efforts and their deceptive messages tainted virtually every information source doctors could rely on, preventing these doctors from making informed treatment decisions. Defendants even infiltrated CME courses, which were attended by physicians who reasonably expected the information they received from the presenters of the CMEs to provide fair and accurate reporting of the most current pain management practices. The CME courses were given with the expectation that physicians, including general practice doctors, could rely on the information presented. Unbeknown to the attendees of the CMEs, much of the curricula were corrupted by Defendants' influence: among other things, the CME presentations exaggerated the benefits and minimized the risks of opioids, while exaggerating the risks and minimizing the benefits of other pain treatment modalities. Defendants targeted not only pain specialists, but also primary care physicians, nurse practitioners, physician assistants, and other non-pain specialists, who were even less likely to be able to assess the companies' misleading statements.

10. To the huge detriment of the public health of Americans, Massachusetts residents, and residents of the Town of Randolph, the Manufacturer Defendants' scheme (which was well-funded, well-organized, and pervasive) was extremely successful. In just a few years, the Manufacturer Defendants managed to jettison decades of well-established and sound medical orthodoxy holding that prescription opioids are far too addictive and potentially debilitating to be used to treat chronic pain. Manufacturer Defendants individually, and working together through their front groups and KOLs, persuaded doctors, patients, and even hospitals that what they had

long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was no longer true, and that the opposite – that the compassionate treatment of pain ***requires*** opioids, the most superior pain management protocol – was the new truth.

11. For example, the Manufacturer Defendants, acting through one of their front groups, the American Pain Society, successfully introduced the "Pain as the Fifth Vital Sign" factor, which, along with respiration rate, body temperature, blood pressure, and pulse rate, is now considered to be a "vital sign" upon which doctors and emergency room personnel assess patients.[4] The Pain as a Fifth Vital Sign campaign was adopted by the Veterans Administration and the Joint Commission (responsible for accreditation of hospitals), both of whom had extensive financial relationships with Purdue at the time of the roll-out of the campaign.

12. The profits of the Manufacturer Defendants skyrocketed. Opioid sales have steadily risen, from $3.8 billion in 2000 to $8 billion in 2010 to $9.6 billion in 2015. Purdue has earned more than ***$35 billion*** in opioid profits since 1996, including more than $3 billion in 2015 (from $800 million in 2006). Purdue's OxyContin sales rose from $45 million in 1996 to $3.1 billion in 2010. Endo Pharmaceuticals has gained a tremendous amount of revenue from opioid sales as well, reaping over $1 billion from Opana ER alone in 2010 and again in 2013.

13. The sales push for greater volume of prescription writing by Manufacturer Defendants came at a lethal cost. The Massachusetts Department of Health has revealed that a patient who receives three months of prescribed opioids is ***30 times*** more likely to overdose and

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[4] *See* Natalia E. Morone & Deborah K. Weiner, *Pain as the 5th Vital Sign: Exposing the Vital Need for Pain Education*, 35 CLINICAL THERAPEUTICS 1728, 1729 (2013). In 2016, the American Medical Association recommended removing pain as the fifth vital sign. *See* Joyce Frieden, *Remove Pain as 5th Vital Sign, AMA Urged*, MEDPAGE TODAY (June 13, 2016), https://www.medpagetoday.com/meetingcoverage/ama/58486 ("'Just as we now know earth [is] not flat, we know that pain is not a vital sign.'").

die than the general population. A patient who stays on prescription opioids for 6-11 months is ***46 times*** more likely to die. Devastatingly, a patient who stays on prescription opioids for a year is ***51 times*** more likely to die.

14. The Distributor Defendants (collectively consisting of Defendants McKesson Corporation ("McKesson"), Cardinal Health, Inc. ("Cardinal"), AmerisourceBergen Drug Corporation ("ABDC"), CVS (as defined below), Rite Aid (as defined below), Walgreens (as defined below), and Walmart (as defined below)) dominate the market share of prescription opioid distribution in the United States.[5]

15. Massachusetts General Laws ("Mass. Gen. Laws") ch. 94C, §12(a) and 105 CMR 700 and the 1970 Controlled Substances Act ("CSA"), 21 U.S.C. §§801, 821-30., require wholesale distributors of "controlled substances" (all the prescription opioids involved in the opioid epidemic and listed in Tables 1-9, *infra*, are either Schedule II or III controlled substances), to register with the Massachusetts Commission of Public Health and the U.S. Drug Enforcement Administration ("DEA") in order to be approved as a vendor of controlled substances.

16. In order to get and retain the coveted registration (without which a wholesale distributor cannot lawfully sell any prescription opioids in the United States), the wholesale distributor has a statutory duty, that mirrors its common law duty, to conduct its business of distributing dangerous drugs in a reasonable and safe manner. Included among these obligations are the duties "to report to [the] DEA suspicious orders for controlled substances and to take other precautions to ensure that those medications would not be diverted into illegal channels." *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 211-12 (D.C. Cir. 2017); 21 C.F.R. §1301.77. Mass. Gen.

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[5] Adam J. Fein, *2016 MDM Market Leaders/Top Pharmaceuticals Distributors*, MDM, https://www.mdm.com/2016-top-pharmaceuticals-distributors (last visited Mar. 4, 2019).

Laws ch. 94C, §12(a)(2) requires the wholesale distributor of prescription drugs to "operate in compliance with applicable federal, state and local laws."

17. Each Distributor Defendant utterly failed to discharge its statutory obligations under Mass. Gen. Laws ch. 94C, §12(a) and 105 CMR 700.006(A) to maintain and monitor a closed chain of distribution and detect, report, inspect, and halt suspicious orders, so as to prevent the misuse or black market diversion of controlled substances, as required under state and federal law. The direct and foreseeable result of the Distributor Defendants' unlawful conduct is that many communities, including the Town of Randolph, have been flooded with an excess supply of pharmaceutical opioids.

18. Each of the "Big Three" Distributor Defendants—McKesson, Cardinal, and ABDC—has been investigated and fined by the DEA for failing to:

(a) operate its mandatory internal oversight system in good faith;

(b) report suspicious orders to the DEA; and

(c) halt the shipment of "suspicious orders for controlled substances" when they were discovered.

19. McKesson Corporation, the largest wholesale distributor in the United States, agreed on January 17, 2017 to pay a $150 million fine to the U.S. Department of Justice ("DOJ") for its violations of the CSA.[6]

20. In late December 2016, Cardinal Health, Inc. agreed to a $34 million fine to "resolve allegations that [it] failed to report to the DEA suspicious orders of Class II [powerful

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[6] *See* Press Release, US DOJ Office of Public Affairs, McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs (Jan. 17, 2017) (available at https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders).

narcotics] by pharmacies located in Central Florida and Maryland."[7] This is the second settlement in less than a decade in which Cardinal Health, Inc. has agreed to allegations by the federal government that it failed to report suspicious opioid orders.

21. Cardinal Health, Inc. settled a lawsuit initiated by the State of West Virginia for $20 million, which alleged violations of the CSA that are similar to its violations in the Commonwealth of Massachusetts. *See State of W. Va. v. AmerisourceBergen Drug Corp.*, No. 12-C-141 (W. Va. Cir. Ct., Boone Cty.). AmerisourceBergen Drug Corporation also agreed to pay West Virginia $16 million for settlement of the same litigation. *See id.*

22. Distributor Defendants CVS (as defined below), Rite Aid (as defined below), Walgreens (as defined below), and Walmart (as defined below) similarly have failed to monitor, control, and prevent the diversion of the opioids that they distribute and dispense. As described below, like the Big Three, many of these National Retail Pharmacies (as defined below) have already been investigated and fined in connection with such failures.

23. The explosion in opioid use and abuse, along with the corresponding explosion in profits for the Defendants, was not due to a medical breakthrough in pain treatment. Instead, it was due, in substantial part – as the National Institutes of Health ("NIH") recognizes – to the "aggressive marketing" of Defendants. The NIH stated:

> Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using

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[7] *See* Press Release, US Attorney's Office of the Middle District of Florida, United States Reaches $34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances Act (Dec. 23, 2016) (available at https://www.justice.gov/usao-mdfl/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under).

medications for different purposes, and aggressive marketing by pharmaceutical companies.[8]

24. Over the past two decades, as the sales of opioids increased, so too did deaths and hospitalizations caused by opioids.[9]

25. Starting in or about 1996 – coinciding with a rapid increase in prescription opioid use for medical purposes – the United States has experienced an opioid epidemic that has been characterized as the worst drug epidemic in its history. An epidemic is defined as a sharp increase in the prevalence of a disease (or diseases) within a discreet period of time.[10] The principal disease associated with the opioid epidemic is opioid addiction, sometimes referred to as "opioid use disorder" or "opioid abuse or dependence."

26. The 2016 Guidelines issued by the U.S. Centers for Disease Control and Prevention ("CDC"), *Guideline for Prescribing Opioids for Chronic Pain* (the "2016 CDC Guidelines"), is a peer-reviewed guideline that is based on scientific evidence. It has defined "opioid addiction," "opioid use disorder," and "opioid abuse or dependence" as a "problematic pattern of opioid use leading to clinically significant impairment or distress . . . manifested by specific criteria such as

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8 *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing Before the U.S. S. Caucus on Int'l. Narcotics Control*, 113th Cong. 2 (2014) ("Volkow Testimony") (testimony of Nora D. Volkow, M.D., Director, National Institute on Drug Abuse), https://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

9 Andrew Kolodny, *et al.*, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANNU. REV. PUB. HEALTH 559 (2015), http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.

10 U.S. DEP'T OF HEALTH AND HUMAN SERVS., CTRS. FOR DISEASE CONTROL AND PREVENTION, PRINCIPLES OF EPIDEMIOLOGY IN PUBLIC HEALTH PRACTICE, AN INTRODUCTION TO APPLIED EPIDEMIOLOGY AND BIOSTATISTICS, 1-72 (3d ed. 2012), https://www.cdc.gov/ophss/csels/dsepd/ss1978/ss1978.pdf.

unsuccessful efforts to cut down or control use and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home."[11]

27. Opioid addiction, like other forms of addiction, is a chronic medical condition. It is treatable, but not curable. Unfortunately, for a variety of reasons, including a shortage of and limitations on resources, the presence of shame and stigma, and the presence of barriers to treatment, only a small percentage of patients who need treatment actually receive the right types of treatment and levels of care, in the right settings, for the right lengths of time. In the absence of proper treatment, the disease of addiction is progressive and frequently fatal. Even with optimal treatment for the optimal time at the optimal setting, opioid addiction tends to be a relapsing disease.

28. According to the CDC, the opioid addiction has led to an epidemic in opioid overdoses, which, in turn, has led to an increase in opioid fatalities. In the period from 1994-2014, the CDC estimated that there were 165,000 overdose deaths in the United States associated with prescription opioid use.[12] Public health authorities estimate that, for every opioid overdose death, there are 30 non-fatal overdoses.[13] Thus, in the period from 1999-2014, an estimated 5 million

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11 Deborah Dowell, *et al.*, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 MORBIDITY AND MORTALITY WKLY. REP. 1, 2 (2016). The current diagnostic manual used by most behavioral health professionals, DSM-V, uses the term "opioid use disorder" to refer to and define what has in the past essentially been referred to as opioid addiction. In this Complaint, Plaintiff will generally use the term "addiction" to refer to opioid use disorder, opioid addiction, and opioid abuse or dependence, unless context dictates otherwise. These diagnoses are "different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped)." *Id.*

12 *Id.* at 2, 18.

13 Andrea Hsu, *Hospitals Could Do More for Survivors of Opioid Overdoses, Study Suggests*, NPR (Aug. 22, 2017), http://www.npr.org/sections/health-shots/2017/08/22/545115225/hospitals-could-do-more-for-survivors-of-opioid-overdoses-study-suggests.

non-fatal opioid overdoses were also likely to have occurred. Of course, there are also untold tens of thousands of people, who are seriously impaired in their ability to function in society by the disease of opioid addiction, who do not necessarily experience overdoses.

29. In 2016, the CDC acknowledged the existence of two opioid epidemics involving addiction and overdoses. Also in 2016, the President of the United States declared that an opioid and heroin epidemic exists in America.[14]

30. The direct correlation between increases in sales of prescription opioids and opioid addiction and overdoses prompted the CDC and other public health authorities to conclude that the principal cause of both opioid epidemics was the unprecedented increase in use of prescription opioids.[15] The CDC gathered data relating to prescription opioid usage using sales of prescription opioids as a measure of prescription opioid usage, and correlated this data with data relating to admissions for treatment of opioid use disorders and overdose deaths. Using this data and analyses, the CDC and other researchers concluded that the daily use of prescription opioids to treat chronic pain has been the principal causative factor driving both epidemics in opioid addiction and overdoses.[16]

31. Public health authorities have also concluded that prescription opioid use is responsible not only for the addiction and overdose epidemics relating directly to prescription opioids, but also for the multi-year surge in non-prescription, illegal opioid use, including the use

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[14] Dowell, *supra* n.11 at 3, 34; *accord* Press Release, Ctrs. for Disease Control and Prevention, CDC Launches Campaign to Help States Fight Prescription Opioid Epidemic (Sept. 25, 2017) (available at https://www.cdc.gov/media/releases/2017/p0925-rx-awareness-campaigns.html) (recognizing "opioid epidemic"); *see* Proclamation No. 9499, 81 Fed. Reg. 65173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

[15] *Id.* at 2.

[16] *Id.*

of heroin and fentanyl. As law enforcement, public health authorities, and the medical profession have begun to limit the improper use of prescription opioids, along with other reasons (including the high price of prescription opioids), which has reduced the supply of prescription opioids for legal use, many prescription opioid users suffering from opioid addiction have turned to heroin available on the black market.[17]

32. As the profits of the Defendants have increased year-after-year, so, too, have the numbers of substance abuse treatment admissions and overdose deaths in the Commonwealth of Massachusetts. The Commonwealth of Massachusetts's skyrocketing drug overdose death rates are consistent with the CDC's findings, with 379 opioid-related deaths in 2000.[18] In 2012, that number nearly doubled with 742 opioid-related deaths.[19] By 2016, opioid-related deaths had skyrocketed to 2,083 deaths, which constituted a 181% increase from 2012 and a staggering 450% increase from 2000.[20] Drug overdose deaths involving synthetic opioids other than methadone more than doubled in just one year between 2014 and 2015.[21] Non-fatal opioid overdoses have

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17 Approximately 80% of individuals who begin using heroin made the transition from initial prescription opioids. Andrew Kolodny, *et al.*, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANNU. REV. PUB. HEALTH 559 (2015); *accord* THE MAYOR'S TASK FORCE TO COMBAT THE OPIOID EPIDEMIC IN PHILADELPHIA, FINAL REPORT AND RECOMMENDATIONS 7 (2017), *available at* http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf.

18 MASS. DEP'T OF PUB. HEALTH, NUMBER OF OPIOID-RELATED OVERDOSE DEATHS, ALL INTENTS BY CITY/TOWN, MA RESIDENTS: 2013-2017, https://www.mass.gov/files/documents/2018/05/22/Opioidrelated%20Overdose%20Deaths%20by%20City%20Town%20-%20May%202018_0.pdf. (last visited February 2019).

19 *Id.*

20 *Id.*

21 *The Massachusetts Opioid Epidemic: A Data Visualization of Findings from the Chapter 55 Report*, MASS. DEP'T OF PUB. HEALTH, http://www.mass.gov/chapter55 (last visited Mar. 4, 2019).

seen a similar rise: between 2011 and 2015, nonfatal overdoses increased by 200%, with the total number of such overdoses exceeding 65,000.[22] Randolph, like the Commonwealth of Massachusetts, has experienced a public health crisis from the skyrocketing opioid addiction and opioid-related overdoses and deaths, as well as the ensuing devastating social and economic consequences. This public health crisis is a public nuisance to the Town because it constitutes unreasonable interference with, and injury to, the public health, safety, peace, and welfare of its residents and the community as a whole.

33. Like the Commonwealth of Massachusetts, the Town of Randolph has been struck particularly hard by the over-prescribing of opioid drugs and the resulting boom in the number of opioid addicts.

34. So, too, have the fatalities increased. For example, in 2013, there were 5 opioid-related overdose deaths in Randolph.[23] In 2015, there were 12 such deaths, constituting a 140% increase.[24] The number of opioid-related fatalities in Randolph between January 1, 2013 and December 31, 2017 was at least 41.

35. The catastrophic effects of each Manufacturer Defendant's unlawful deceptive marketing scheme and each Distributor Defendant's wanton, willful, reckless, and negligent violation of its statutory and common law gatekeeping role to ensure the supply of opioids into communities be maintained at safe levels, are only getting worse.

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22 MASS. DEP'T. OF PUB. HEALTH, AN ASSESSMENT OF FATAL AND NONFATAL OPIOID OVERDOSES IN MASSACHUSETTS (2011 – 2015) (2017), https://archives.lib.state.ma.us/bitstream/handle/2452/734807/on1001341902.pdf?sequence=1&isAllowed=y.

23 *Number of Opioid-Related Overdose Deaths*, *supra* n.18.

24 *Id.*

36. The Manufacturer Defendants' scheme of deception and the Distributor Defendants' failure to conduct their business in a lawful and reasonable manner in compliance with state common law and state and federal statutory law have flooded the Town with opioids and created a greatly increased number of opioid addicted individuals that has strained the Town's resources to cope with the epidemics. In addition to the enormous costs to the Town's ability to provide traditional municipal services (*infra* at ¶¶48-53, the Town has also been forced to create and fund (both directly and indirectly) collaborative programs and interventions to respond to the epidemics, including without limitation naloxone programs, prevention and addiction education programs, and "take-back" programs for opioids and other prescription drugs. *See generally* §IV.F, *infra*. These programs, and others, are well beyond the scope of what has ever been considered a municipal service.

37. Plaintiff brings this lawsuit to enjoin the violations of all the Defendants, obtain damages for the monies it has been forced to expend as a result of the Defendants' wrongful conduct, and require the Defendants to abate the public nuisance they created.

38. Defendants' conduct has violated and continues to violate Chapter 93A and false advertising laws. Mass. Gen. Laws ch. 93A, §2 and ch. 94, §190. Additionally, Defendants' conduct constitutes a common law public nuisance, common law fraud, negligent misrepresentation, negligence, and civil conspiracy and has resulted, and continues to result, in unjust enrichment. Plaintiff does not allege that any product was defective and expressly does not bring product liability claims.

39. To redress and enjoin Defendants' previous and continuous violations of the law, the Town of Randolph brings this action seeking abatement, restitution, damages, treble damages,

disgorgement of unlawful profits, civil penalties, attorneys' fees and costs permitted by law, and equity.

II. JURISDICTION AND VENUE

40. This Court has personal jurisdiction over each Defendant because each Defendant carries on a continuous and systematic part of its general business within Massachusetts, has transacted substantial business with Massachusetts entities and residents, and has caused harm in Massachusetts as a result of the specific business activities complained of herein.

41. Venue is proper in this Court because the Town is in Norfolk County. Mass. Gen. Laws ch. 223, §§1, 8.

III. PARTIES

A. Plaintiff

42. Plaintiff Town of Randolph provides many municipal services to foster the safety, health, and well-being of its residents, including: schools; police, fire, and law enforcement services; public health, safety and assistance services for families, youth, elders, veterans and persons in need; and public parks, conservation areas, libraries and recreational activities. Pursuant to the Randolph Town Charter, Randolph is a city form of government but is known as the "Town of Randolph." Due to the severity and nature of the public nuisance created and fueled by Defendants' wrongful conduct, the Town has been forced to expend enormous amounts of taxpayer dollars to meet the needs of its citizens and its integrity as a town, to provide many services that are well beyond those traditionally considered to be municipal services in order to address the opioid epidemic, thereby diverting tax dollars away from other resources.

43. Plaintiff Town of Randolph is a 10.5 square mile municipality that is located in Norfolk County. The Town of Randolph has a population of approximately 32,000 people according to the U.S. Census data. Randolph is the most diverse community on the South Shore

of Massachusetts, and is among the most diverse communities in Massachusetts. Randolph is a vibrant and historic suburban residential community supplemented by retail, light manufacturing and service industries.

44. The Town of Randolph participates in the Massachusetts Group Insurance Commission ("GIC") medical and health insurance programs for its employees and retirees. The Town also provides a Workers' Compensation program for all its employees.

45. The Town brings this action on its own behalf and as *parens patriae* in the public interest on behalf of its residents.

B. Defendants

Defendants Purdue Pharma L.P. d/b/a Purdue Pharma (Delaware) Limited Partnership, Purdue Pharma Inc., and The Purdue Frederick Company, Inc.

46. Defendant Purdue Pharma L.P. ("PPL"), registered and doing business in Connecticut as Purdue Pharma (Delaware) Limited Partnership, is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

47. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

48. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

49. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the Town of Randolph, including the following:

Table 1 - Purdue Opioids

Drug Name	Chemical Name
OxyContin	Oxycodone hydrochloride extended release
MS Contin	Morphine sulfate extended release

Table 1 - Purdue Opioids

Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Buprenorphine
Hysingla ER	Hydrocodone bitrate
Targiniq ER	Oxycodone hydrochloride and naloxone

50. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up three-fourfold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

51. In 2007, Purdue settled criminal and civil charges brought against it by the DOJ for misbranding OxyContin and agreed to pay the United States over $600 million – at the time, one of the largest settlements with a drug company for marketing misconduct – as well as a sweeping set of injunctive relief requiring the Defendant to cease its unlawful and deceptive marketing practices. *United States of America v. Purdue Frederick Co., Inc.*, No. 1:07CR00029, Plea Agreement (W.D. Va. May 10, 2007). Simultaneously, Purdue settled an action brought by 27 state attorneys general for $20 million and further injunctive relief.

52. Upon information and belief, Purdue has violated most, if not all, of its commitments under its consent decrees with the government.

Defendants Teva Pharmaceuticals and Cephalon, Inc.

53. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

54. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

55. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute, and sell both brand-name and generic versions of opioids nationally and in Randolph, including the following:

Table 2 – Cephalon Opioids

Drug Name	Chemical Name	Form
Actiq	Fentanyl citrate	Lollipop or lozenge
Fentora	Fentanyl citrate	Buccal tablet, like a smokeless tobacco plug

56. In September 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") for its misleading promotion of Actiq (and two other drugs) and agreed to pay $425 million in fines, damages, and penalties.

Defendant Collegium Pharmaceutical, Inc.

57. Defendant Collegium Pharmaceutical, Inc. ("Collegium") is a Virginia corporation with its principal place of business in Stoughton, Massachusetts.

58. Collegium manufactures, promotes, sells, and distributes opioids nationally and in Randolph, including the following opioids, as well as their generic versions:

Table 3 – Collegium Opioids

Drug Name	Chemical Name	Form
Xtampza ER	Oxycodone	Tablet extended release
Nucynta (from 2018)	Tapentadol	Tablet
Nucynta ER (from 2018)	Tapentadol ER	Tablet

59. As of January 10, 2018, Collegium has signed a commercialization agreement with Depomed, Inc., which allows Collegium to market the opioid products Nucynta and Nucynta ER.[25]

Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals, Inc.

60. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

61. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

62. Defendant Ortho-McNeil-Janssen Pharmaceuticals Inc. ("OMP") (now known as Janssen Pharmaceuticals, Inc.) is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

63. OMP was formerly known as Janssen Pharmaceutica, Inc.

64. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs, and Janssen Pharmaceuticals' profits inure to J&J's benefit. J&J has a well-known and proudly advertised reputation and company-wide business practice of strictly controlling the development and marketing of pharmaceuticals by its affiliates.

65. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Randolph, including the following:

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[25] *Depomed Announces Closing of NUCYNTA Commercialization Agreement with Collegium Pharmaceutical,* GLOBENEWSWIRE, Jan. 10, 2018, https://globenewswire.com/news-release/2018/01/10/1286734/0/en/Depomed-Announces-Closing-of-NUCYNTA-Commercialization-Agreement-With-Collegium-Pharmaceutical.html.

Table 4 – Janssen Opioids

Drug Name	Chemical Name	Form
Duragesic	Fentanyl	Transdermal Patch
Nucynta (prior to 2015)	Tapentadol	Tablet
Nucynta ER (prior to 2015)	Tapentadol ER	Tablet

66. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. In April 2015, Janssen Pharmaceuticals transferred to Depomed, Inc. the right to license Nucynta and Nucynta ER in the United States.[26] Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals, Inc.

67. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

68. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

69. EHS and EPI (collectively, "Endo") manufacture, promote, distribute, and sell opioids nationally and in Randolph, including the following:

Table 5 – Endo Opioids

Drug Name	Chemical Name	Form
Opana ER	Oxymorphone hydrochloride extended	Tablet
Opana	Oxymorphone hydrochloride and aspirin	Tablet
Percodan	Oxycodone hydrochloride and acetaminophen	Tablet release

[26] *Janssen Pharmaceuticals, Inc. Completes Divestiture of U.S. License Rights to NUCYNTA® (tapentadol), NUCYNTA® ER (tapentadol) Extended–Release Tablets and NUCYNTA® (tapentadol) Oral Solution to Depomed, Inc.*, Apr. 2, 2015, https://www.prnewswire.com/news-releases/janssen-pharmaceuticals-inc-completes-divestiture-of-us-license-rights-to-nucynta-tapentadol-nucynta-er-tapentadol-extended-release-tablets-and-nucynta-tapentadol-oral-solution-to-depomed-inc-300060522.html.

Percocet	Oxycodone and acetaminophen	Tablet

70. Opioids comprised approximately $403 million of Endo's overall revenue of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc. ("Qualitest"), including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

71. A reformulated Opana ER that had been approved in 2012 was removed from the market in June 2017, at the request of the FDA, which found that "the benefits of the drug may no longer outweigh its risks." The FDA stated, "the FDA determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER."[27]

Defendants Allergan plc f/k/a Actavis plc, Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.

72. Allergan Finance, LLC is a privately held Nevada corporation with its principal place of business in Parsippany, New Jersey. Allergan Finance, LLC was formerly known as Actavis, Inc., which in turn was formerly known as Watson Pharmaceuticals, Inc. Allergan Finance, LLC is an indirect wholly owned subsidiary of Allergan plc, which is incorporated in Ireland with its principal place of business in Dublin, Ireland. Allergan Finance, LLC and its predecessors, affiliates, and/or combining entities, including, but not limited to, Actavis, Inc.,

[27] Press Release, FDA, FDA Requests Removal of Opana ER for Risks Related to Abuse (June 8, 2017) (available at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm).

Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. are collectively referred to as "Actavis."

73. Actavis manufactures, promotes, sells, and distributes opioids nationally and in Randolph, including the following opioids, as well as their generic versions:

Table 6 – Actavis Opioids

Drug Name	Chemical Name	Form
Kadian	Morphine sulfate	Tablet extended release
Norco	Hydrocodone bitartrate and acetaminophen	Tablet

74. Kadian is an extended-release tablet for "the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. and began marketing Kadian in 2009.

Defendants Mallinckrodt PLC and Mallinckrodt LLC

75. Mallinckrodt PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt LLC is a limited liability company organized and existing under the laws of the State of Delaware. Since 2013, Mallinckrodt LLC has been a wholly owned subsidiary of Mallinckrodt PLC; prior to 2013, it was a wholly owned subsidiary of Irish public limited company Covidien PLLC (formerly known as Tyco Healthcare). Mallinckrodt PLC and Mallinckrodt LLC are referred to collectively as "Mallinckrodt."

76. Mallinckrodt manufactures, promotes, sells, and distributes opioids nationally and in Randolph, including the following opioids, as well as their generic versions:

Table 7 – Mallinckrodt Opioids

Drug Name	Chemical Name	Form
Exalgo	Hydromorphone hydrochloride	Tablet extended release
Xartemis	Oxycodone hydrochloride and acetaminophen	Tablet extended release
Roxicodone	Oxycodone hydrochloride	Tablet

77. Mallinckrodt also manufactures, markets, and sells generic oxycodone, of which it is one of the largest manufacturers.

78. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

Defendant Insys Therapeutics, Inc.

79. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

80. Since 2012, Insys has been manufacturing and selling the following opioid:

Table 8 – Insys Opioids

Drug Name	Chemical Name	Form
Subsys	Fentanyl	Sublingual spray absorbed through mucous in the mouth

81. Subsys is a highly addictive synthetic opioid mouth spray approved for treatment of cancer pain in patients who are tolerant of other opioids. Subsys is a form of fentanyl – a narcotic up to 50 times more powerful than heroin and 100 times more powerful than morphine.

82. According to Insys's 2016 Annual Report, Subsys was the most prescribed transmucosal immediate-release fentanyl, with 42% market share, which translates to nearly $300 million in annual U.S. product sales for Insys – an increase of 270% in sales over just a year. *See* Insys Therapeutics, Inc., Annual Report at 1 (Form 10-K) (Apr. 3, 2017).

83. The broad sales of Subsys raised suspicions over Insys's sales practices, especially because it appeared that only 1% of Subsys sales were generated by oncologists, and the only approved use of Subsys is for a subset of cancer patients. Subsequent investigations revealed that Insys executives (including Individual Defendant John Kapoor named below) devised and sanctioned blatantly unlawful methods to increase sales for off-label uses to the profound harm, including death, of many patients.

84. On December 16, 2016, six former Insys executives were indicted by Carmen Ortiz, the U.S. Attorney for the District of Massachusetts, for their participation in an alleged "nationwide conspiracy" to give healthcare providers kickbacks in exchange for the improper prescribing of Subsys. On October 24, 2017, a superseding indictment named and incorporated Individual Defendant Kapoor for his role in Insys's alleged "nationwide conspiracy." According to the superseding indictment, the former head of sales for Insys, Alec Burlakoff, and others ran a sophisticated scheme that used pharmacy data to identify doctors who prescribed a lot of opioids. They then bribed the doctors with offers of cushy speaking engagements to increase their Subsys prescriptions even further and to write a minimum number of prescriptions at a minimum dose to generate as many insured refill orders as possible "without regard to the medical needs of ... Subsys patients." (Quoting superseding indictment).[28] On November 28, 2018, Burlakoff pleaded guilty to one count of racketeering conspiracy and agreed to cooperate with prosecutors in their case against Insys.

85. A Senate investigation into the opioid crisis generally began with an investigation into Insys, specifically. The conclusion to the initial report, *Fueling an Epidemic*, states that Insys

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[28] Alex Johnson, *Ex-Drug Company Executive Pleads Guilty to Bribing Doctors*, NBC NEWS (Nov. 28, 2018), https://www.nbcnews.com/news/amp/ncna941466.

"has repeatedly employed aggressive and likely illegal techniques to boost prescriptions for its fentanyl product Subsys . . . [that] included actions to undermine critical safeguards in the prior authorization process[.]"[29]

86. The Senate investigation confirmed anecdotal evidence that sales representatives were instructed to encourage their sales "targets" (the physician, physician's assistant, nurse practitioner, or staff of the medical group with whom they met) to start the patient on a higher dosage of Subsys than was approved by the FDA. The sales representatives were told to explain to the physician that the reason to start the patient at a higher dose was to improve the pain relief outcome to the patient, but the true reason was to increase Insys's revenue. There is anecdotal evidence that the "motto" among the sales force in many regions of the country, including Massachusetts, was "start them high and hope they don't die." The investigation uncovered a chilling letter from an Insys sales representative to the CEO confirming that was indeed a commonly used refrain among the sales force at Insys.

87. For ease of reference, the following is a table of all Manufacturer Defendants and their principal opioid products:

Table 9

Purdue Opioids	
Drug Name	**Chemical Name**
OxyContin	Oxycodone hydrochloride extended release
MS Contin	Morphine sulfate extended release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Buprenorphine

[29] U.S. CONG. S. COMM. ON HOMELAND SEC. AND GOV'T. AFFAIRS, FUELING AN EPIDEMIC: INSYS THERAPEUTICS AND THE SYSTEMIC MANIPULATION OF PRIOR AUTHORIZATION (2017), *available at* https://www.hsdl.org/?abstract&did=803959.

Table 9

Hysingla ER	Hydrocodone bitrate	
Targiniq ER	Oxycodone hydrochloride and naloxone	
Cephalon Opioids		
Drug Name	**Chemical Name**	**Form**
Actiq	Fentanyl citrate	Lollipop or lozenge
Fentora	Fentanyl citrate	Buccal tablet, like a smokeless tobacco plug
Collegium Opioids		
Drug Name	**Chemical Name**	**Form**
Xtampza	Oxycodone	Tablet extended release
Nucynta (from 2018)	Tapentadol	Tablet
Nucynta ER (from 2018)	Tapentadol ER	Tablet
Janssen Opioids		
Drug Name	**Chemical Name**	**Form**
Duragesic	Fentanyl	Transdermal Patch
Nucynta (prior to 2015)	Tapentadol	Tablet
Nucynta ER (prior to 2015)	Tapentadol ER	Tablet
Endo Opioids		
Drug Name	**Chemical Name**	**Form**
Opana ER	Oxymorphone hydrochloride extended	Tablet
Opana	Oxymorphone hydrochloride and aspirin	Tablet
Percodan	Ocycodone hydrochloride and acetaminophen	Tablet release
Percocet	Oxymorphone hydrochloride and acetaminophen	Tablet
Actavis Opioids		
Drug Name	**Chemical Name**	**Form**
Kadian	Morphine sulfate	Tablet extended release
Norco	Hydrocodone bitartrate and acetaminophen	Tablet

Table 9

Mallinckrodt Opioids		
Drug Name	**Chemical Name**	**Form**
Exalgo	Hydromorphone hydrochloride	Tablet extended release
Xartemis	Oxycodone hydrochloride and acetaminophen	Tablet extended release
Roxicodone	Oxycodone hydrochloride	Tablet
Insys Opioids		
Drug Name	**Chemical Name**	**Form**
Subsys	Fentanyl	Sublingual spray absorbed through mucous in the mouth

Defendant McKesson Corporation

88. Defendant McKesson Corporation ("McKesson") is registered with the Secretary of the Commonwealth of Massachusetts as a company incorporated under the laws of Delaware, with its principal place of business in San Francisco, California. McKesson is the largest pharmaceutical distributor in North America; it delivers approximately one-third of all pharmaceuticals used in North America. McKesson conducts business in Massachusetts by distributing prescription opioids to hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions ("Retail End Users"). McKesson is subject to federal and state reporting obligations with respect to the distribution of controlled substances in Massachusetts. *See* 21 U.S.C. §§801, *et seq.*; Mass. Gen. Laws ch. 94C, §12(a) and 105 CMR 700.006(A).

Defendant AmerisourceBergen Drug Corporation

89. Defendant AmerisourceBergen Drug Corporation ("ABDC") is registered with the Secretary of the Commonwealth of Massachusetts as a company incorporated under the laws of Delaware, with its principal place of business in Chesterbrook, Pennsylvania. ABDC is the second largest pharmaceutical distributor in North America. ABDC conducts business in Massachusetts

by distributing prescription opioids to Retail End Users. ABDC is subject to federal and state reporting obligations with respect to the distribution of controlled substances in Massachusetts. *See id.*

Defendant Cardinal Health, Inc.

90. Defendant Cardinal Health, Inc. ("Cardinal") is registered with the Secretary of the Commonwealth of Massachusetts as a company incorporated under the laws of Ohio, with its principal place of business in Dublin, Ohio. Cardinal is the third largest distributor of pharmaceuticals in North America. Cardinal conducts business in Massachusetts by distributing prescription opioids to Retail End Users. Cardinal is subject to federal and state reporting obligations with respect to the distribution of controlled substances in Massachusetts. *See id.*

CVS Defendants

91. Defendant CVS Health Corporation is a Delaware corporation with its principal place of business in Rhode Island. Defendant CVS Pharmacy, Inc., a Rhode Island corporation with its principal place of business in Rhode Island, owns and/or manages retail pharmacies and is registered with the Massachusetts Secretary of State's Office. CVS Health Corporation and CVS Pharmacy, Inc. are collectively referred to herein as "CVS." CVS, through its various registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in the Randolph area.

Rite Aid Defendants

92. Defendant Rite Aid Corporation is a Delaware corporation with its principal place of business in Pennsylvania. Defendant Rite Aid of Massachusetts, Inc., a Massachusetts corporation with its principal place of business in Pennsylvania, owns and/or manages retail pharmacies and is registered with the Massachusetts Secretary of State's Office. Rite Aid

Corporation and Rite Aid of Massachusetts, Inc. are collectively referred to herein as "Rite Aid." Upon information and belief, Rite Aid, through its various registrant subsidiaries and affiliated entities, conducted business as a licensed wholesale distributor and distributed opioids in the Randolph area until *at least* 2018, when it transferred 1,932 stores and related assets, and three distribution centers, to Defendant Walgreens Boots Alliance, Inc.

Walgreens Defendants

93. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business in Illinois. Upon information and belief, Defendant Walgreen Eastern Co., Inc., a New York corporation with a principal place of business in Illinois, manages retail pharmacies in Massachusetts. Defendant Walgreens Mail Service, L.L.C., a Delaware limited liability company with a principal place of business in Illinois, owns and/or manages retail pharmacies and is registered with the Massachusetts Secretary of State's Office. Defendant Walgreens of Massachusetts, L.L.C., a Massachusetts limited liability company with a principal place of business in Massachusetts, owns and/or manages retail pharmacies and is registered with the Massachusetts Secretary of State's Office. Defendant Walgreens Specialty Pharmacy, L.L.C., a Delaware limited liability company with a principal place of business in Illinois, owns and/or manages retail pharmacies and is registered with the Massachusetts Secretary of State's Office. Walgreens Boots Alliance, Inc., Walgreen Eastern Co., Inc., Walgreens Mail Service, L.L.C., Walgreens of Massachusetts, L.L.C., and Walgreens Specialty Pharmacy, L.L.C. are collectively referred to herein as "Walgreens." Walgreens, through its various registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walgreens distributed prescription opioids throughout the United States, including in the Randolph area.

Walmart Defendants

94. Defendant Walmart Inc., formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Arkansas, and is registered with the Massachusetts Secretary of State of State's Office. Defendant Wal-Mart Stores East, Inc., a Delaware corporation with a principal place of business in Arkansas, owns and/or manages retail pharmacies and is registered with the Massachusetts Secretary of State's Office. Defendant Wal-Mart Stores East, L.P., a Delaware limited partnership with a principal place of business in Arkansas, owns and/or manages retail pharmacies and is registered with the Massachusetts Secretary of State's Office. Defendant Wal-Mart.com USA, L.L.C., a California limited liability company with a principal place of business in Arkansas, owns and/or manages retail pharmacies and is registered with the Massachusetts Secretary of State's Office. Walmart Inc., Wal-Mart Stores East, Inc., Wal-Mart Stores East, L.P., and Wal-Mart.com USA, L.L.C. are collectively referred to herein as "Walmart." Walmart, through its various registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Walmart distributed prescription opioids throughout the United States, including in the Randolph area.

95. CVS, Rite Aid, Walgreens and Walmart are collectively referred to herein as the "National Retail Pharmacies." Cardinal, McKesson, ABDC and the National Retail Pharmacies are collectively referred to as the "Distributor Defendants."

Individual Defendants

96. Defendant John Kapoor ("Kapoor") is the founder, former Chairman of the board of directors, and Chief Executive Officer ("CEO") of Insys. He remains the majority stockholder of the company. Kapoor was indicted in Boston federal court on October 24, 2017 on charges of conspiracies to commit racketeering pursuant to 18 U.S.C. §1962(d), mail fraud pursuant to 18

U.S.C. §1349, wire fraud pursuant to 18 U.S.C. §1349, and to violate the Anti-Kickback Law pursuant to 18 U.S.C. §371. The criminal trial commenced on January 25, 2019 and is continuing. The indictment arose from the practice of Insys paying kickbacks to doctors to write large numbers of prescriptions, which, upon information and belief, was devised by Individual Defendant Kapoor, along with other Insys executives. Kapoor is a citizen of the State of Arizona.

97. Defendant Richard Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant R. Sackler resides in Connecticut.

98. Defendant Jonathan Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant J. Sackler resides in Connecticut.

99. Defendant Mortimer D.A. Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant M. Sackler resides in New York.

100. Defendant Kathe Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant K. Sackler resides in Connecticut.

101. Defendant Ilene Sackler Lefcourt has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant I. Sackler Lefcourt resides in New York.

102. Defendant Beverly Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant B. Sackler resides in Connecticut.

103. Defendant Theresa Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon Information and belief, Defendant T. Sackler resides in the United Kingdom.

104. David Sackler has been a member of the board of Purdue Pharma Inc. since the 2012. Upon information and belief, Defendant D. Sackler resides in New York.

105. Defendants R. Sackler, J. Sackler, M. Sackler, K. Sackler, I. Sackler Lefcourt, B. Sackler, T. Sackler, and D. Sackler are collectively referred to herein as the "Sackler Family Defendants."

IV. FACTUAL ALLEGATIONS

A. The Scientific Basis for Pain-Relieving and Addictive Properties of Opioids

1. Similarity Between Prescription Opioids and Heroin

106. The medicinal effects of opium, an extract from the flowering poppy plant, to relieve pain and often cause euphoria, have been known for thousands of years.

107. In the early 1800s, a German pharmacist, Freidrich Sertürner, isolated a molecule from opium and named it "morphine"—after an ancient Greek god associated with sleep and dreams—for its hypnotic, as well as analgesic, properties.

108. The late 1800s and early 1900s saw a plethora of semi-synthetic opioids that were easily derived by manipulating the basic morphine structure. Semi-synthetic opioids produce a more rapid effect than morphine because they cross the blood-brain barrier more easily.

109. One of the first semi-synthetic opioids, heroin, began being manufactured in the late 19th century. In 1914, the Harrison Narcotics Tax Act imposed a tax on those making, importing, or selling any derivative of opium. By the 1920s, physicians were aware of the highly addictive nature of opioids and tried to avoid treating patients with them. Heroin became illegal in 1924.

110. Other semi-synthetic opioids, such as oxycodone, hydrocodone, oxymorphone and hydromorphone, continued to be designed in labs and approved for restricted medical uses. All

the opioids sold by Manufacturer Defendants Purdue, Endo, Actavis, Collegium, and Mallinckrodt fall within these categories. *See supra* at ¶87, Table 9.

111. In 1960, a fully synthetic opioid, named fentanyl, was synthesized by Dr. Paul Janssen in Belgium.

112. Fentanyl has been produced in various forms, including lollipops (Actiq) and a spray absorbed through the mouth (Subsys). The products of Cephalon, Janssen, and Insys (listed *supra* at ¶87, Table 9) are fentanyl, or fentanyl-based, synthetic opioids.

113. All these opioids, including semi-synthetic and fully synthetic opioids, work on a patient in very similar ways. They react with opioid receptors in the brain of the patient and are considered "full agonists." "Agonists interact with a receptor to produce a maximal response from that receptor."[30]

114. When a full agonist opioid interacts with the opioid receptor, there is a cascade of reactions, ultimately leading to an increase in the release of dopamine in the brain.[31]

115. Opiate receptor stimulation by opioids can relieve pain and produce euphoria. These effects have been understood for millennia as properties of opium.

116. However, a known result of the physiological process for all the opioids (just as it has been for millennia with the opium from the poppy plant) is that if taken daily, tolerance and dependence develop rapidly.

117. Tolerance results in the need to take higher doses to achieve the same effect.

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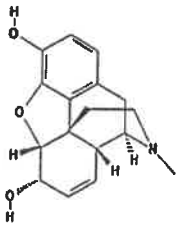
30 Hasan Pathan & John Williams, *Basic Opioid Pharmacology: An Update*, 6 BRIT. J. PAIN 11 (2012), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4590096/.

31 Nora D. Volkow, *et al.*, *Neurobiologic Advances from the Brain Disease Model of Addiction*, 374 NEW ENG. J. MED. 363 (2016), http://www.nejm.org/doi/full/10.1056/NEJMra1511480#t=article.

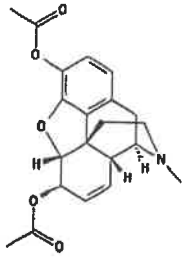
118. Dependence results in dysphoria, increased pain sensitivity, anxiety, and flu-like symptoms when opioids are discontinued. These symptoms lead to cravings for continue use.

119. Commonly prescribed opioids produce effects that are indistinguishable from the effects produced by other semi-synthetic opioids. Commonly used prescription opioids are also quite similar to heroin on a molecular level, as shown in the charts below:

Morphine[32]



Heroin[33]



Oxycodone[34]

(sold as Percocet, OxyContin)

Hydrocodone[35]

(sold as Vicodin)

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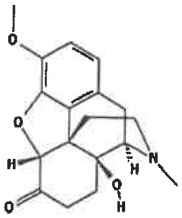
32 Sunghwan Kim, *et al.*, *Compound Summary for CID 5288826: Morphine*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5288826 (last updated Mar. 2, 2019).

33 Sunghwan Kim, *et al.*, *Compound Summary for CID 5462328: Diamorphine*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5462328 (last updated Mar. 2, 2019).

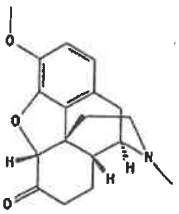
34 Sunghwan Kim, *et al.*, *Compound Summary for CID 5284603: Oxycodone*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5284603 (last updated Mar. 2, 2019).

35 Sunghwan Kim, *et al.*, *Compound Summary for CID 5284569: Hydrocodone*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5284569 (last updated Mar. 2, 2019).



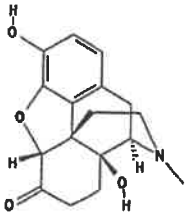
Oxymorphone[36]

(sold as Opana)



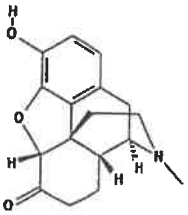
Hydromorphone[37]

(sold as Dilaudid)



Fentanyl[38]

(sold as Subsys)



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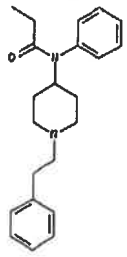
[36] Sunghwan Kim, *et al.*, *Compound Summary for CID 5284604: Oxymorphone*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5284604 (last updated Mar. 2, 2019).

[37] Sunghwan Kim, *et al.*, *Compound Summary for CID 5284570: Hydromorphone*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5284570 (last updated Mar. 2, 2019).

[38] Sunghwan Kim, *et al.*, *Compound Summary for CID 3345: Fentanyl*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/3345 (last updated Mar. 2, 2019).



120. It is simple to see from these charts how chemically similar the natural morphine, heroin, and semi-synthetic opioids are to one another. The opioid pain relievers ("OPRs") all share the same five-ring structure that allows them to react with opioid receptors in the brain. While fentanyl and other synthetic opioids do not share the same five-ring structure, they nevertheless interact with opioid receptors in the brain the same way. Dr. Andrew Kolodny, Senior Scientist and Co-Director of Opioid Policy Research at the Heller School for Social Policy and Management, and co-founder of Physicians for Responsible Opioid Prescribing, called prescription opioids "heroin pills":[39]

> Like heroin, most OPRs are made from opium. Their molecular structure is nearly identical to that of heroin and the effects they produce in the brain are indistinguishable from heroin. What this means is that when we talk about OPRs, we are essentially talking about "heroin pills."

121. Commonly prescribed opioid analgesics have the same pain-relieving, euphoria-inducing, intensely addictive qualities of morphine and heroin.

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[39] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing Before the U.S. S. Caucus on Int'l. Narcotics Control* at 2, 113th Cong. (2014) (statement of Andrew Kolodny, M.D., Chief Medical Officer, Phoenix House Foundation), https://www.drugcaucus.senate.gov/sites/default/files/Kolodny%20Testimony.pdf.

122. A Columbia University study found that experienced heroin users preferred the effects of oxycodone over the effects of heroin.[40]

2. Biology of Why a Person with a Prescription Opioid Addiction Frequently Turns to Street Drugs

123. With daily use of opioids, in as little as one week, patients can experience withdrawal symptoms if opioids are discontinued (commonly referred to as "dependence"). Once dependent, cessation of use produces deeply unpleasant symptoms, such as nausea, vomiting, headaches, tremors, insomnia, and pain.

124. Dr. Kolodny has explained the effect of opioids as akin to "hijack[ing] the brain's reward system," which, in turn, convinces a user that "the drug is needed to stay alive."[41]

125. When under the continuous influence of opioids over a period of time, patients grow tolerant to the analgesic or pain-relieving effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction he or she has become accustomed to – up to, and including, doses that are considered to be "frighteningly high."[42] At higher doses, the effects of withdrawal are more substantial, and the risk of addiction increases. The FDA has acknowledged that available data suggests a relationship between increased doses and the risk of adverse effects.[43]

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40 Sandra D. Comer, *et al.*, *Relative Abuse Liability of Prescription Opioids Compared to Heroin in Morphine-Maintained Heroin Abusers*, 33 NEUROPSYCHOPHARMACOLOGY 1179 (Jun. 20, 2007), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3787689.

41 David Montero, *Actor's death sows doubt among O.C.'s recovering opioid addicts*, THE ORANGE CNTY. REGISTER (Feb. 4, 2014), https://www.ocregister.com/2014/02/04/actors-death-sows-doubt-among-ocs-recovering-opioid-addicts/.

42 Mitchell H. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170 ARCHIVES OF INTERNAL MED. 1422 (2010), available at https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/225880?redirect=true.

43 Volkow Testimony, *supra* n.8.

126. As addiction science shows, once an individual is addicted to any of these products, a series of biochemical reactions and physiological changes in the brain make it very difficult to break the addiction, even if the patient desperately wants to do so. These known brain changes in addicted persons also explain why addiction is a relapsing disease.

127. As the New England Journal of Medicine explains:

> This attenuated release of dopamine renders the brain's reward system much less sensitive to stimulation by both drug-related and non-drug-related rewards. As a result, persons with addiction no longer experience the same degree of euphoria from a drug as they did when they first started using it. It is for this same reason that persons with addiction often become less motivated by everyday stimuli (e.g., relationships and activities) that they had previously found to be motivating and rewarding. Again, it is important to note that these changes become deeply ingrained and cannot be immediately reversed through the simple termination of drug use (e.g., detoxification).[44]

128. As addiction deepens, the changes in the brain of the addict become more profound. The deadened mood affect and pre-occupation with continued use to the exclusion of previously pleasurable activities are aggravated by a lessened ability to control impulses. Further:

> [t]he changes that occur in the reward and emotional circuits of the brain are accompanied by changes in the function of the prefrontal cortical regions, which are involved in executive processes. Specifically, the down-regulation of dopamine signaling that dulls the reward circuits' sensitivity to pleasure also occurs in prefrontal brain regions and their associated circuits, seriously impairing executive processes, among which are the capacities for self-regulation, decision making, flexibility in the selection and initiation of action, attribution of salience (the assignment of relative value), and the monitoring of error.[45]

129. Recent research on the brains of addicted individuals makes clear why that person would substitute heroin for prescription opioids, and further, why the changes in the individual's brain caused by the addiction to prescription opioids makes it almost impossible to resist the need for continued use, even to the point of death.

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44 Volkow, *et al.*, *supra* n.31.

45 *Id.*

130. In short, the progression of addiction is, first, the initial pain relief and feeling of well-being or euphoria experienced by the patient. Next is the craving for more and more of the substance, since the dopamine rewards system has been hijacked and the patient is incapable of experiencing everyday joys. Even greater and more frequent amounts of the opioid do not work, since the patient's dopamine reward system is broken. As addiction proceeds, the patient becomes increasingly incapable of thinking through the situation, since his prefrontal cortical regions have become affected. Therefore, a person who has become addicted to opioids feels compelled to continue using and will switch to heroin if it is easier and less expensive to obtain.

3. Biology of Why a Person with an Opioid Addiction Frequently Turns to Crime[46]

131. Opioid addiction is different from other chronic diseases. The opioid-addicted individual will behave in ways that appear anti-social. Even a threat of severe punishment is insufficient to keep them from continuing their opioid use. They will give up everything and everyone they have ever cared about to maintain their opioid supply. The anti-social behavior that opioid-addicted individuals engage in is not driven by character flaws or moral failing. Instead, the behavior is secondary to the development of addiction. Once addicted, good people will behave in ways they never could have imagined.

132. When an opioid is taken regularly, regions of the brain that modulate behavior and control our higher functions like judgment, decision making, and self-control over our actions begin to change in ways that may be irreversible. In effect, opioids hijack critical regions of the

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[46] Nora D. Volkow, *et al.*, *Addiction: Decreased Reward Sensitivity and Increased Expectation Sensitivity Conspire to Overwhelm the Brain's Control Circuit*, 32 BIOESSAYS 748 (2010), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1002/bies.201000042.

brain causing a loss of free will, resulting in the need to continue using an opioid to avoid feeling dysphoria.

133. Opioid addiction is a disease of exposure. Repeated use of opioids, even when taken exactly as prescribed, can result in addiction. The sharp increase in opioid prescribing over the past 20 years has led to parallel increases in opioid addiction and overdose deaths. Overprescribing causes addiction directly in patients prescribed opioids. And overprescribing causes addiction indirectly, as patients' prescriptions are borrowed or shared with family members, friends, or acquaintances.

B. Lack of Evidence that Long-Term Opioid Use Was a Valid Pain Treatment

134. Manufacturer Defendants have always been aware that there was no real evidence of the safety and efficacy of opioids for long-term use. To the contrary, there was evidence that, with long-term use, opioid drugs would become less effective because of tolerance to the pain-relieving effects.

135. A 2006 study-of-studies found that opioids as a class did not demonstrate improvement in "function" over other non-addicting treatments. It stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids."[47]

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[47] Andrea D. Furlan, *et al.*, *Opioids for Chronic Noncancer Pain: A Meta-Analysis of Effectiveness and Side Effects*, 174 CAN. MED. ASS'N J. 1589 (2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/pdf/20060523s00017p1589.pdf. This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. *See* Karen H. Seal, *et al.*, *Association of Mental Health Disorders with Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan*, 307 J. AM. MED. ASS'N 940 (2012), https://jamanetwork.com/journals/jama/fullarticle/1105046.

136. Endo's own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30% to 39%); insomnia (9% to 22%); and self-described fair or poor health (24% to 34%).

137. In the fall of 2009, as a pain specialist noted in an article titled *Are we making pain patients worse?*, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[48]

138. Workers' compensation data has also long revealed the lack of evidence for the efficacy of opioids for long-term chronic pain. Claims involving workers who take opioids are almost four times as likely to reach costs of over $100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would still be on work disability one year later. A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim.

139. In the face of this body of evidence and medical orthodoxy questioning the efficacy and safety of opioids, the Manufacturer Defendants mounted their disinformation campaign to open the market for their drugs, despite the known risk of addiction.

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48 Andrea Rubenstein, *Are We Making Pain Patients Worse?*, SONOMA MED., Fall 2009.

C. Campaign of Misinformation and Unlawful Conduct by Manufacturer Defendants

1. Summary of Manufacturer Defendants' Disinformation Campaign

140. Manufacturer Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the late 1990s and continues to the present, set out to and succeeded in reversing the popular and medical understanding of opioids. Chronic opioid therapy – the prescribing of opioids to treat chronic pain long-term – is now a commonplace and highly dangerous practice in the United States.

141. Since Insys did not begin selling its fentanyl-based product, Subsys, until 2012, and Collegium did not begin selling its oxycodone-based product, Xtampza ER, until April 2016, they did not participate in the activity preceding that date. Nevertheless, both Insys and Collegium did profit from the collusive campaign of other Manufacturer Defendants to change medical orthodoxy solely for reasons of greed, rather than a scientific basis, and they continue to misrepresent the safety and efficacy of opioid treatment for chronic pain.

142. To accomplish this reversal, Manufacturer Defendants spent hundreds of millions of dollars: (a) developing and disseminating ***seemingly truthful*** scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids for treating chronic pain; (b) funding, assisting, encouraging, and directing KOLs to deliver scripted talks, publish misleading studies, and present CMEs that disseminated false and incomplete information to medical practitioners; (c) infiltrating the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; (d) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to as "Front Groups") that developed misleading educational materials and treatment guidelines that were then

distributed by Distributor Defendants, urging doctors to prescribe, and patients to use, opioids long-term to treat chronic pain; (e) deploying sales representatives, who visited doctors and other prescribers, who marketed their opioids for "non-indicated" or off-label purposes, not approved by the FDA, thereby violating 21 U.S.C. §§331(a)-(b), 352(a), and misrepresented the benefits and risks of their opioid; and (f) targeting public ads to vulnerable populations, such as the elderly and veterans.

143. Manufacturer Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured opioids' serious risks and adverse outcomes, including the risks of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as other, non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and prevalence of withdrawal symptoms. There is not, and there never has been, reliable scientific evidence to support Manufacturer Defendants' marketing claims. There has long been, and there continues to be, substantial scientific evidence that these claims are false.

2. False Messaging

a. Drug Companies Must Deal Honestly with Patients, Consumers, and Governmental Payors

144. Like every other business in Massachusetts, pharmaceutical manufacturers have a duty to deal honestly and truthfully with consumers and to refrain from using unfair and deceptive acts to boost profits at the consumer's expense.

145. A drug company's representations about its drug must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.

146. Furthermore, drug companies are not permitted to sell any drugs that are "misbranded," which means, among other things, that the "label" cannot be false or misleading. "Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[49] The term "accompanying" includes promotional materials – posters, websites, brochures, books, etc. that are disseminated by, or on behalf of, the manufacturer of the drug.[50] Thus, Manufacturer Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

147. Labeling is misleading if it is not based on substantial evidence, materially misrepresents the benefits of a drug, or omits material information about or minimizes the frequency or severity of a product's risks. Promotion that fails to present the most important risks of a drug as prominently as its benefits lacks fair balance and is therefore deceptive.

148. Drug companies are also prohibited from distributing evidence or information about a drug's safety or efficacy, or presenting conclusions that "clearly cannot be supported by the results of the study."[51] Drug companies further must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[52]

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49 21 U.S.C. §321(m).

50 *See id.*; Annotation, Notes of Decisions, Accompanying the Article, Labeling, 21 U.S.C.A. § 321 (West).

51 21 C.F.R. §99.101(a)(4).

52 21 C.F.R. §202.1(e)(6)(ii).

149. The Manufacturer Defendants' responsibilities to not engage in false, untrue, misleading, and deceptive statements of material fact to physicians, consumers, payors, and Plaintiff are consistent with their duties under Massachusetts false advertising laws and Chapter 93A, as well as the FD&C Act. Plaintiff expressly denies that the reference to the FD&C Act in this Complaint means that any claims "arise under" federal law within the meaning of 28 U.S.C. §1331.

150. Manufacturer Defendants long maintained that prescription opioids carry little to no risk of addiction, when they knew that not to be true. For example, Purdue claimed that the risk of addiction was negligible, even though its own studies had shown that between 8% and 13% of OxyContin patients became addicted.

151. Manufacturer Defendants have said that specific characteristics of their drugs made them less addictive, when there was no evidence to support their assertions. For example, Endo marketed Opana ER as being crush-resistant and, as a result, hard to abuse and harder to become addicted to. In fact, Endo knew that there was no evidence to support this assertion. Sales representatives for Purdue, Janssen, Endo and Actavis promoted their drugs as having "steady-state" properties with the intent and expectation that prescribers would understand this to mean that their drugs caused less of a rush or a feeling of euphoria, which can trigger misuse and addictions.

152. Cephalon-sponsored *Treatment Options: A Guide for People Living with Pain* (American Pain Foundation, 2007) stated that addiction is limited to extreme cases of unauthorized dose escalations, getting opioids from multiple sources, or theft. In truth, Cephalon knew there was no basis for this depiction that addiction occurred only in rare cases.

153. Manufacturer Defendants have maintained that addiction risk can be managed by the prescribing physician by asking patients to fill out a questionnaire to assess their risk of addiction (known as "screening"). Actavis trained its sales force to advise prescribers that they can use risk screening tools to limit the development of addiction. However, there is not, and there never has been, evidence to suggest that such screening is reliable.

154. Manufacturer Defendants falsely suggested or even blatantly proclaimed that withdrawal from opioids was not a problem. Actavis trained its sales force to assert that discontinuing opioid therapy can be handled "simply" and done at home, with the withdrawal period approximately taking a week, even in addicted patients. Janssen training materials between 2009 and 2011 repeatedly proclaimed "low incidence of withdrawal symptoms" as a "core message" for their sales force. In addition to claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients 2-4 days after discontinuing opioid use. Janssen knew, or should have known, that these symptoms peak earlier than that for most patients.

155. Contrary to Manufacturer Defendants' assertions, opioids have been found time and again to be addictive. A patient's fear of the unpleasant effects of discontinuing opioids, combined with the negative reinforcement during a period of actual withdrawal, can push a patient to seek further opioid treatment – even where ineffective or detrimental to quality of life – simply to avoid the deeply unpleasant effects of withdrawal.

b. Falsehood: No Upper Limit on Amount of Opioids to Consumer

156. Manufacturer Defendants have misrepresented and even denied entirely the dangers posed by large doses of opioids. Manufacturer Defendants claimed that dosages could be escalated continuously to match high pain tolerance, even though studies showed that such escalation could be deadly. This false advice has been disseminated even though the Manufacturer

Defendants, their executives, researchers, and sales staff have knowledge that increasing a dosage or starting a patient with a high dosage may be fatal. *See supra* at ¶¶86; *infra* at ¶159, 325, 331, §IV.C.9.

157. This falsehood is of particular concern because none of the Manufacturer Defendants' opioids has a cap on dosage. Thus, the guidance of manufacturers (and the medical community, informed by manufacturers) has a critical role to play in preventing overdose.

158. There is not now, and there never has been, any scientifically based support for the Manufacturer Defendants' statements that there are no upper limits for opioids.

159. High doses pose real risk. The 2016 CDC Guidelines states, in pertinent part: "[b]enefits of high-dose opioids for chronic pain are not established," while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[53] They further state that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages[.]" As a result, the CDC advised doctors to "avoid increasing dosage" above 90 morphine milligram equivalents per day.

160. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he or she has become accustomed – up to, and including, doses that are "frighteningly high."[54] *Supra* at ¶125. At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

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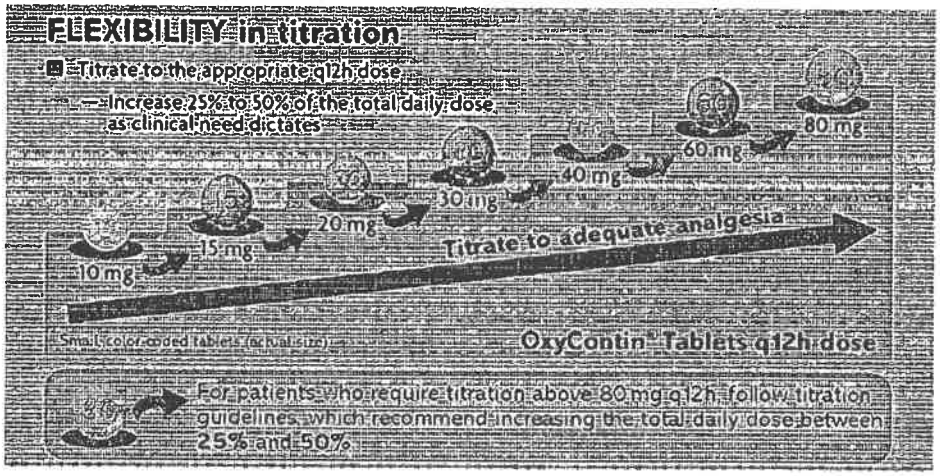
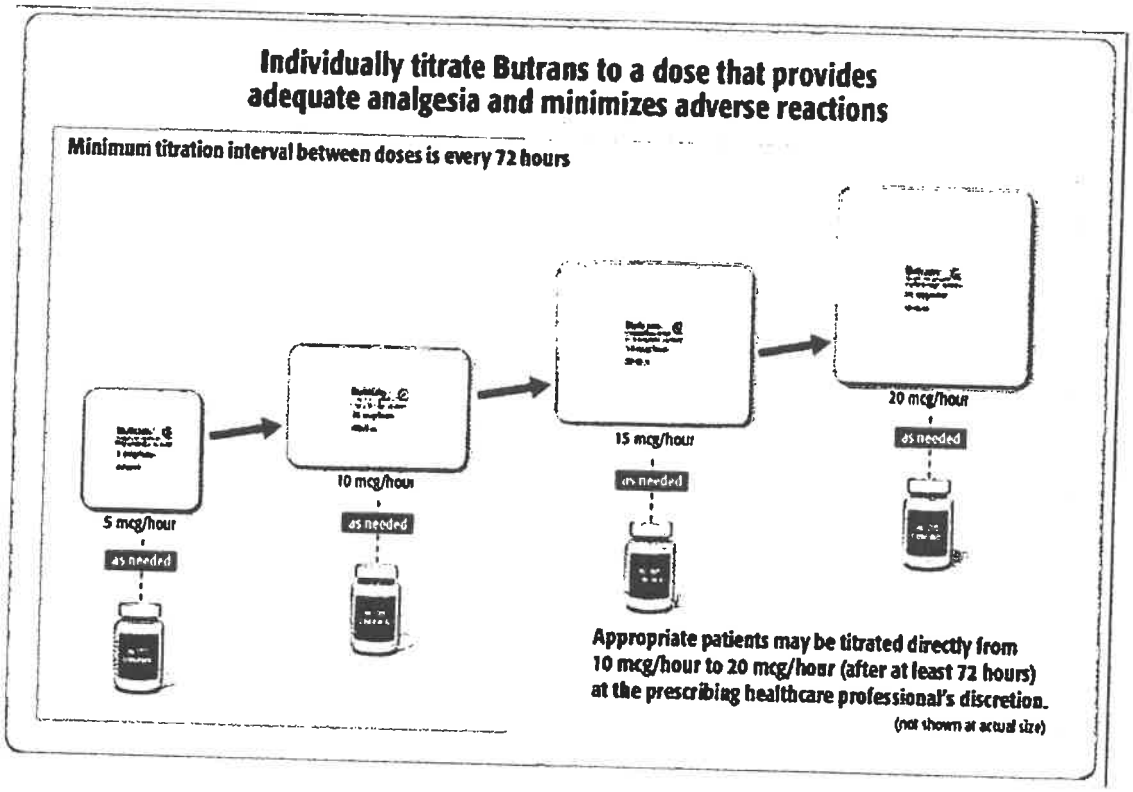
53 Dowell, *et al.*, *supra* n.11.

54 Katz, *supra* n.42.

161. Upon information and belief, Purdue required its sales representatives to "practice verbalizing the titration [dosing] message." Purdue believed increasing titration was a key marketing objective and even monitored the pace at which doctors increased doses of its opioids. Sales representatives were warned when the doses were not increased fast enough by their target physicians. This ruthless sales tactic was memorialized by Purdue in a sales guide, entitled, "Initiation, Conversion, and Titration Discussions with the Appropriate Selling Tools."

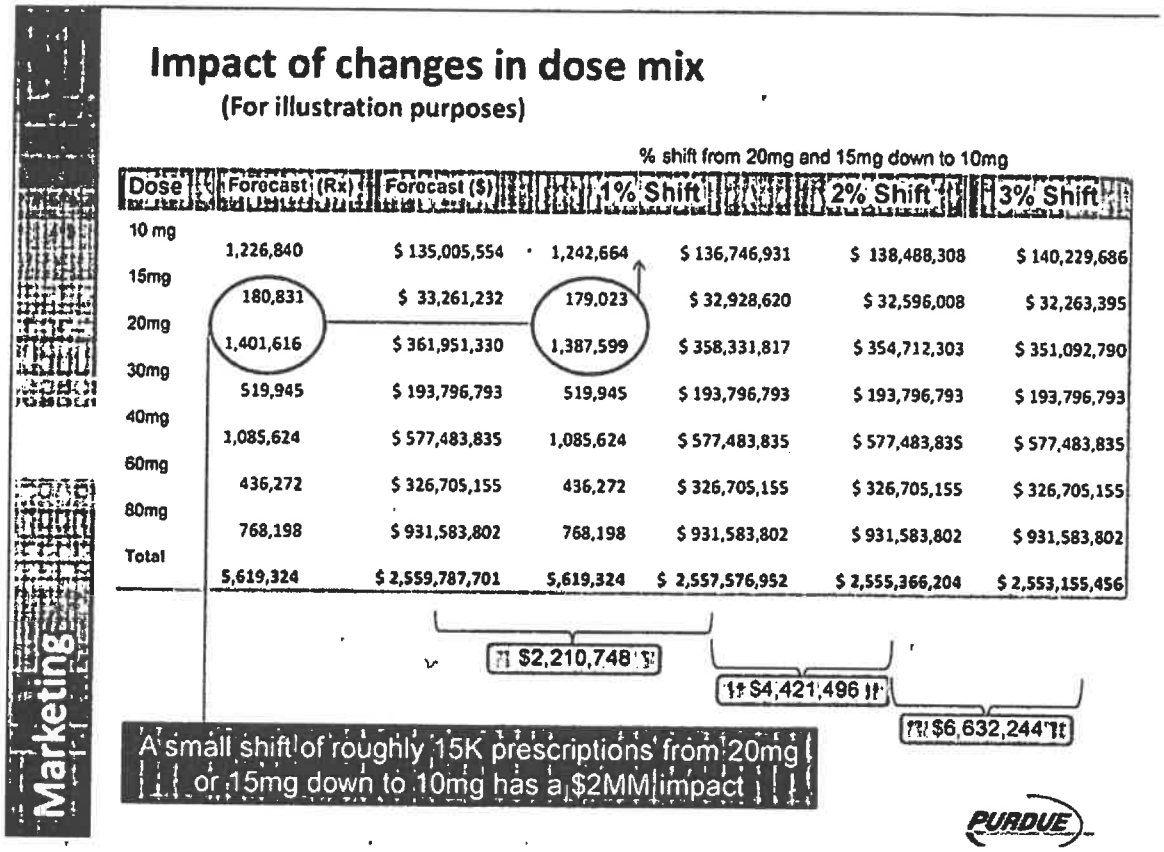


Purdue opioid promotion from 2008.



Purdue opioid promotion from 2013.

162. Upon information and belief, rather than applaud public health efforts, Purdue lambasted in internal documents such efforts to limit total daily dose and length of therapy by saying such efforts "would ***negatively impact business***." [Emphasis added.] To push back against the public demands in 2014 to decrease dosage, Purdue defensively pursued a "strategic initiative" to fight back and "maintain 2013 dose mix."

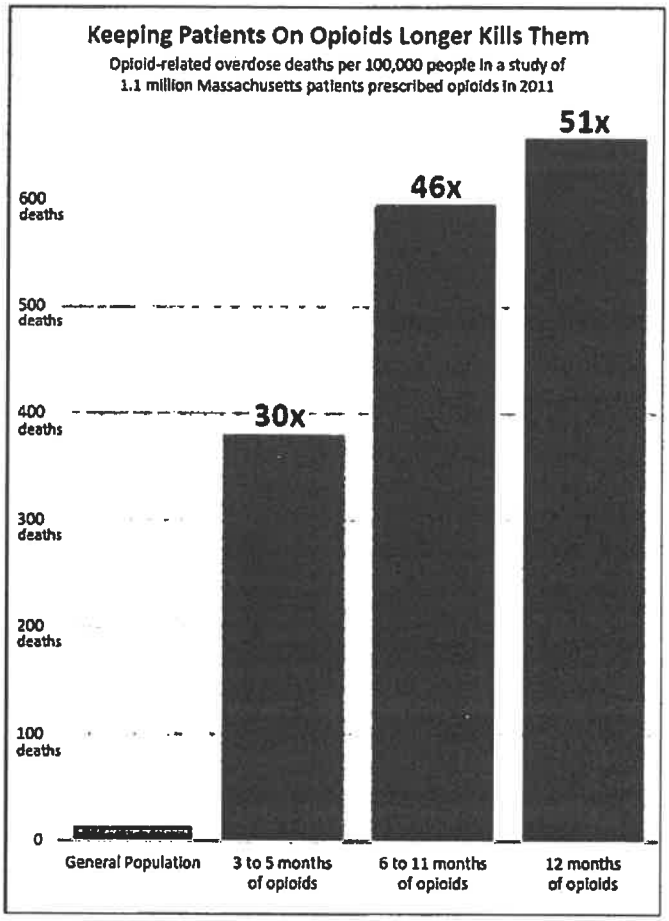


Purdue internal strategy presentation from 2012.

163. According to Purdue's 2015 Price List, a patient taking Purdue's 80 mg OxyContin pill twice a day for a week earned Purdue $210. If that same patient could be kept on the drug for a year, Purdue received far more money: $10,959. Purdue's confidential internal analysis, revealed in the June 12, 2018 Mass AG Complaint, "found that there is greater loss [in sales] in the 60mg and 80mg strengths (compared to other strengths) when we don't make primary sales calls." Purdue's business plans emphasized that "OxyContin is promotionally sensitive, specifically with the higher doses, and recent research findings reinforce the value of sales calls."

164. Purdue promoted the assertion that "[o]pioid dose was not a risk factor for opioid overdose," even while it admitted in internal private documents that "it is very likely" that there is a "dose-related overdose risk in [chronic non-cancer pain] patients on [chronic opioid therapy]."

165. Purdue's deception about the risk of higher doses was deliberate. Purdue recorded in an internal "Publication Plan" that its' "KEY MESSAGES" would say that "dose alone" is not "the reason for overdose deaths," and "opioid overdose is controlled by good prescribing practice and patient monitoring, not by arbitrary dosage limitations."



AGO graph from Massachusetts Department of Public Health data.

c. Falsehood: Opioids Are the Best Solution

166. Manufacturer Defendants have consistently exaggerated the benefits and downplayed the side effects of opioids as compared to other analgesics. Specifically, Manufacturer Defendants have ignored the effects of long-term opioid therapy, which include addiction, hyperalgesia, hormonal dysfunction, decline in immune function, increased bone fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interaction with other medication

taken to treat disorders frequently co-existing with chronic pain. At the same time, Manufacturer Defendants have greatly exaggerated the incidence of side-effects and the risk of death from medicines, such as aspirin or ibuprofen, technically known as non-steroidal anti-inflammatory drugs ("NSAIDs"). Manufacturer Defendants have suggested 10,000-20,000 annual deaths are attributable to NSAIDs, when the real number is approximately 3,200 and shrinking.[55]

167. On the contrary, there is evidence that opioid drugs are less effective at treating chronic pain and may worsen patients' health. As noted, a comprehensive study in 2006 found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Rather, the study concluded: "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."[56] The above study and similar ones that were antithetical to the position of the Manufacturer Defendants were simply not presented by the KOLs in their speeches to practitioners, in the lectures presented at CMEs controlled by the Manufacturer Defendants, or in the Front Groups used to disseminate the Manufacturer Defendants' false message that opioids are a superior pain treatment.

168. The Manufacturer Defendants knew their disparagement of NSAIDs and other analgesics was unfounded. Indeed, Endo's own internal research shows that patients taking opioid-based pain medicines specifically reported higher rates of obesity, insomnia, and self-described fair or poor health.

169. The Manufacturer Defendants deceptively exaggerated the risks associated with high doses of acetaminophen and NSAIDs (such as aspirin and ibuprofen) and instead pushed their

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55 *See* Courtney Krueger, *Ask the Expert: Do NSAIDs Cause More Deaths Than Opioids?*, 13 PRACTICAL PAIN MGMT. 10 (Nov./Dec. 2013), https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ask-expert-do-nsaids-cause-more-deaths-opioids.

56 Furlan, *et al.*, *supra* n.47.

opioids, which they claimed to have "no ceiling dose" and are "the gold standard of pain medications."

d. Falsehood: The Promise of a Pain-Free Life and Vigorous Existence

170. Manufacturer Defendants misrepresented that opioids improve functioning over time. For example, Janssen sponsored a patient education guide in 2009, *Finding Relief: Pain Management for Older Adults*, which states, as a fact, that "opioids may make it easier for people to live normally."

171. Purdue also conceived and funded third-party publications to proclaim that opioids give patients the "quality of life we deserve." This was a lie. Purdue's internal documents admit that "Purdue has no clinical studies or other substantial evidence demonstrating that a Purdue Product will improve the quality of a person's life." There is not, and there never has been, any data to support the claim that they do so; in fact, there is data to suggest that long-term opioid usage reduces functioning. Data from workers' compensation claims indicates that there is a negative correlation between opioid prescriptions and a person returning to work.[57]

172. The 2016 CDC Guidelines (*supra* at ¶26) state that "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy." The CDC further found that "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

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[57] *See, e.g.*, Cindy L. Kidner, *et al.*, *Higher Opioid Doses Predict Poorer Functional Outcome in Patients with Chronic Disabling Occupational Musculoskeletal Disorders*, 91 J. BONE JOINT SURG. AM. 919 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2665041/pdf/JOBOJOS9130919.pdf.

e. Falsehood: Tapering Is an Effective Way to Manage Any Withdrawal

173. Manufacturer Defendants also falsely represent that withdrawal is easily managed, for example, by tapering off a patient's dosage. For instance, Endo's CME, *Persistent Pain in the Older Adult*, taught prescribers that withdrawal can be avoided by tapering off dosage by 10-20% per day for ten days.

174. The 2010 Mallinckrodt/C.A.R.E.S. publication, *Defeat Chronic Pain Now!*, advised potential opioid users that tolerance to opioids is "easily remedied," and that "[a]ll patients can be safely taken off opioid medication if the dose is slowly tapered down by their doctor."[58]

175. Janssen's training materials asserted that Nucynta ER has a low incidence of withdrawal symptoms, based on a study of withdrawal symptoms two to four days after discontinuing use (when, in fact, the symptoms peak much earlier).

176. On its current website, PrescribeResponsibly.com, in an article titled *What a Prescriber Should Know Before Writing the First Prescription*, Janssen states that opioid addiction "can usually be managed" with such tools as Opioid Agreements between the prescribing physician and patient.

177. There is no reliable data, nor has there ever been, supporting the statements made by each Manufacturer Defendant that gradual tapering would alleviate the risk of withdrawal.

f. Falsehood: Pseudoaddiction

178. Pharmaceutical manufacturers tried to dismiss signs of addiction in patients by using the term "pseudoaddiction," invented by Dr. David Haddox, later Vice President of Health

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58 BRADLEY S. GALER & CHARLES E. ARGOFF, DEFEAT CHRONIC PAIN NOW! (2010).

Policy at Purdue. Pseudoaddiction was a term used for patients showing signs of addiction, and Defendants explained that what these patients were actually exhibiting was "under-treated pain."

179. With no reliable data, the Manufacturer Defendants grabbed hold of the concept of pseudoaddiction, with the intent and result that treating physicians would ignore signs of actual addiction in their patients (such as seeking early refills, agitation, etc.). Instead of advising the treating physician that the patient is likely in the throes of addiction, the Manufacturer Defendants advocated that the patient is still undertreated and should be prescribed a higher potency of the opioid.

180. A pamphlet, entitled *Clinical Issues in Opioid Prescribing* (2008), urged doctors to look for pseudoaddiction:

> ***A term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug-seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.***

181. In another pamphlet, *Providing Relief, Preventing Abuse: A reference guide to controlled substances prescribing practices* (2008), Purdue admonished doctors that "[u]ndertreatment of pain is a serious problem" and "pain should be treated aggressively." Purdue stated: "Fact[] About Addiction: 'Misunderstanding of addiction and mislabeling of patients as addicts results in unnecessary withholding of opioid medications.'"

182. Purdue released a second edition of *Providing Relief, Preventing Abuse* in 2011, which continued to urge higher doses and added a new deception about the scientific "literature": "***The term pseudoaddiction has emerged in the literature to describe the inaccurate interpretation of [drug-seeking] behaviors in patients who have pain that has not been effectively treated.***" This revised pamphlet and the claims it disseminated cited to no scientific or

medical evidence that supported pseudoaddiction as a diagnosis separate from addiction. The pamphlet failed to disclose that all of the cited "literature" included was linked to organization and doctors paid by Purdue.

183. Purdue also urged doctors to prescribe higher doses in a Purdue-sponsored book, *Responsible Opioid Prescribing* (2011), which again suggested that patients, who appear to be addicted, were instead "receiving an inadequate dose" and needed more drugs. In Purdue's *Opioid Clinical Management Guide* (2009), Purdue told doctors that the greatest risk of addiction was giving patients ***too little*** of its addictive drugs: "The primary risk factor for misuse is uncontrolled or inadequately treated pain."

184. Janssen sponsored, funded, and edited a website publication, entitled *Let's Talk Pain*, which stated "pseudoaddiction refers to patient behaviors that may occur when pain is under-treated[.] . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

185. While the term "pseudoaddiction" is no longer prevalent and not currently posted on any of the Manufacturer Defendants' websites, it was in common use and widely disseminated to physicians through at least 2012. Upon information and belief, as a result of the Manufacturer Defendants' false information campaign, the signs of addiction in opioid-treated patients are still being misconstrued as pseudoaddiction in the community of practicing physicians, including those physicians in Massachusetts who serve the population of the Town of Randolph

186. There never was any scientifically valid evidence for the concept of pseudoaddiction. The Manufacturer Defendants knew there was no scientific basis for the concept and their statements about it were false when made.

3. Means of Disinformation

187. Manufacturer Defendants strengthened the effects of their misinformation by disseminating it through varied sources in a number of settings, targeting both doctors and patients.

188. Manufacturer Defendants have poured significant resources into branded advertisements for their own particular opioids. In 2011, Manufacturer Defendants spent over $14 million advertising in medical journals, including $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.[59]

189. These advertisements have run in publications aimed at pain specialists (*e.g.*, Journal of Pain, Clinical Journal of Pain), as well as those aimed at the entire medical community (*e.g.*, Journal of the American Medical Association).

190. These advertisements have contained misleading claims about Manufacturer Defendants' opioid products. For example, a 2005 Purdue advertisement in the JOURNAL OF PAIN described OxyContin as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that *There Can Be Life With Relief*, falsely suggesting (on both counts) that OxyContin provides effective long-term pain relief and functional improvement. Endo's Opana ER was advertised with photos of people engaged in demanding jobs, suggesting that the drug could provide long-term relief and functional improvement.

191. Since Insys entered the opioid pain market in 2012, after many of these means to disseminate false information were already under way, it is not known at this time to what extent Insys participated in them. Upon information and belief, Insys was able to effectively sell Subsys

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[59] While Actavis spent less than $100,000 and Cephalon spent nothing on medical advertisement in 2011, these companies' expenditures peaked earlier, with Actavis spending $11.7 million in 2005 and Cephalon spending about $4 million over 2007 and 2008.

off-label due to the wide dissemination of misinformation propagated by the other Manufacturer Defendants.

192. Since Collegium made only minimal sales of its opioid product before April 2016, it is not known at this time to what extent Collegium participated in the dissemination of the false information before that time. However, in its marketing effort to sell its opioid product, Xtampza ER, and the opioid products Nucynta and Nucynta ER, which it markets under a licensing agreement, Collegium continues to utilize many of the discredited marketing methods used by other Manufacturing Defendants, including a heavy use of detailers (targeted especially to the high-decile prescribers) to spread deceptions about the safety of opioids on a one-to-one bases, use of KOLs, and sponsorship of Front Groups, such as the American Pain Foundation (*infra* at ¶¶226, 256-65, §IV.C.9), and mischaracterizes the epidemic as "an abuse or misuse of opioid" rather than "an over-use of opioids," the true cause of the epidemic. In its March 7, 2018 Form 10-K SEC filing ("March 2018 Form 10-K"), Collegium stated as follows:

> Chronic pain, typically defined as pain that lasts beyond the healing of an injury or that persists longer than three months, is a worldwide problem with serious health and economic consequences. . . . Common types of chronic pain include lower back pain, arthritis, headache, and face and jaw pain. The prevalence of chronic pain is expected to rise in the future, as the incidence of associated illnesses such as diabetes, arthritis and cancer increases in the aging population.
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> * * *
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> Prescription opioids remain the primary treatment for chronic pain.[60]

a. Unsupported Research

193. Manufacturer Defendants have misrepresented scientific research and evidence surrounding the addictiveness of their pharmaceutical products.

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60 Collegium Pharm., Inc., Annual Report at 5 (Form 10-K) (Mar. 7, 2018).

194. Manufacturer Defendants led people to reasonably believe that they had tested the safety and efficacy of opioids for long-term use by creating a body of false, misleading, and unsupported literature about opioids that appeared to be the result of independent, objective research, and was thus more likely to shape the perceptions of prescribers, patients, and payors.

195. Manufacturer Defendants coordinated the timing and publication of manuscripts, abstracts, posters and oral presentations, and educational materials in peer-reviewed journals and other publications to support the launch and sales of their drugs. Manufacturer Defendants' internal documents show plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort, "fast-track" application journals, which they could use if the pending paper was rejected everywhere else.

196. Manufacturer Defendants worked to ensure that favorable articles were disseminated and cited widely in medical literature, even where references distorted the significance or meaning of the underlying study. One of the most frequently used distortions is the instance of a five-sentence letter written to the NEW ENGLAND JOURNAL OF MEDICINE ("NEJM") in 1980 by Dr. Hershel Jick and his assistant, Ms. Jane Porter.

197. In 1980, Dr. Jick and his assistant, Ms. Porter, who both worked at the Boston University Medical Center, sent the Porter/Jick Letter to the prestigious NEJM:

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

Jane Porter
Hershel Jick, M.D.
Boston Collaborative Drug
Surveillance Program
Boston University Medical Center
Waltham, MA 02154.[61]

198. Manufacturer Defendants and their Front Groups have twisted this letter and misused it as scientific confirmation for their assertion that widespread and long-term opioid use does not pose a substantial threat of addiction. The Manufacturer Defendants knew, but failed to disclose, the material information that undermined the validity of the five-sentence letter for the sweeping proposition for which it was cited.

199. Manufacturer Defendants knowingly misrepresented the findings and scientific value of the letter in several ways:

(a) By omitting the fact that Ms. Porter and Dr. Jick's observations were made in a letter to the editor, and implying – or outright stating – that the results were the published results of a peer-reviewed scientific clinical trial study, they misrepresented the scientific validity of its findings;

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[61] Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980), www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

(b) Based on when the letter was written, in 1980, the use of opioids being described in the letter could only have been for acute pain or end-of-life care because medical practice at the time prohibited opioids from being used to treat chronic pain. Nevertheless, Manufacturer Defendants cited the Porter/Jick Letter as evidence for the proposition that opioids pose a low risk of addiction in all contexts, including long-term use for chronic pain;

(c) Since the Porter/Jick Letter is not based on a clinical trial, there is no level of confidence that patients were regularly being monitored for signs of addiction. Thus, there may have been false negatives;

(d) The letter is written about patients who were given a few opioid doses ***in a hospital***, rather than those who were given prescriptions to take home. Nonetheless, it was trumpeted by Manufacturer Defendants as scientific evidence that opioids pose a low risk of addiction when used long-term; and

(e) There is no evidence that these patients were followed up with after leaving the hospital regarding the presence of any addiction. But it was cited by Manufacturer Defendants as showing that opioids pose no long-term risk of addiction.

200. Manufacturer Defendants mis-cited the Porter/Jick Letter again and again as evidence of the minimal risk of addiction from using opioids as a treatment for chronic pain, despite its limited credibility and the existence of much more significant evidence to the contrary.

201. Two papers funded by Purdue in 1998 showed that between 8% and 13% of patients studied subsequently became addicted to opioids. Ignoring this study, the Porter/Jick Letter was cited and relied upon in two CME courses put on by Purdue and Endo in 2012 to support the assertion that opioids are not addictive.

202. The Porter/Jick Letter was not extensively cited as evidence of opioids' low risk of addiction until it first appeared in a 1986 paper by the American Pain Society, one of Defendants' Front Groups. From there, its use as a tool of misinformation mushroomed. It has been cited over 900 times, in contrast to the 11 other letters to the editor contemporaneously published in NEJM, which were cited a median of 11 times.

203. Dr. Hershel Jick, the primary author, later stated that his own letter had been misused and distorted. He has said that he is "mortified that that letter to the editor was used as an excuse to do what these drug companies did," referring to the fact that "they used this letter to spread the word that these drugs were not very addictive."[62]

204. A 2017 statement in the NEJM (probably the first of its kind) was published as a meta-study on the misuse of the letter. It says that the letter "was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy," which statement "contributed to the North American opioid crisis[.]"[63]

205. The 2017 study reports that 80.8% of articles citing the 1980 letter did not mention that it was limited to the hospital setting and 72.2% of articles citing it used it to support the conclusion that addiction is rare in patients treated with opioids.

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62 Derek Hawkins, *How a Short Letter in a Prestigious Journal Contributed to the Opioid Crisis*, WASH. POST (Jun. 2, 2017), https://www.washingtonpost.com/news/morning-mix/wp/2017/06/02/how-the-opioid-crisis-traces-back-to-a-five-sentence-scholarly-letter-from-1980/?utm_term=.836d02c52301.

63 Pamela T.M. Leung, *et al.*, *A 1980 Letter on the Risk of Opioid Addiction*, 376 NEW ENG. J. MED 2194 (2017), https://www.nejm.org/doi/10.1056/NEJMc1700150.

206. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[64]

207. Manufacturer Defendants also worked to discredit or bury negative information. Manufacturer Defendants – often with the help of third-party consultants – targeted a broad range of media to disseminate their message, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters disparaging reports of the link between opioids and addiction.

208. Manufacturer Defendants' strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits, and superiority of opioids for chronic pain relief, resulting in distorted prescribing patterns.

b. Key Opinion Leaders

209. Manufacturer Defendants used KOLs (who are generally distinguished physicians and neutral sources of guidance in their medical field) as sources of pro-opioid misinformation for regular practicing doctors, including those in Massachusetts treating Randolph residents.

210. The KOLs have been central to the Manufacturer Defendants' diffuse marketing efforts. KOLs have written, consulted on, edited, and lent their names to books and articles and given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines strongly encouraging the use of opioids to treat chronic pain and the boards of pro-opioid advocacy groups and professional societies that develop, select, and

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64 Marilynn Marchione, *Painful Words: How a 1980 Letter Fueled the Opioid Epidemic*, AP NEWS (May 31, 2017), https://www.apnews.com/9307eb6e8b3c4970bb2a6344a09b0170.

present CMEs. Manufacturer Defendants were able to exert control over each of these modalities through their KOLs.

211. In exchange for these services of the KOLs, Manufacturer Defendants provided them with money, prestige, recognition, research funding, and avenues to publish. This positioned the KOLs to exert even more influence in the medical community.

212. Opioid-makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its efforts to persuade the public and regulators that tobacco was not addictive or dangerous. For example, tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in-line with industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous, and later described himself as a pawn in the industry's campaign.

213. Manufacturer Defendants cultivated and promoted only those KOLs who could be relied upon to help broaden the chronic pain opioid therapy market. Manufacturer Defendants selected, funded, and elevated those doctors whose public positions were unequivocally supportive of using opioids to treat chronic pain. These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities not directly funded by the drug companies.

214. Manufacturer Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Manufacturer Defendants did not disseminate the publications of doctors critical of the use of chronic opioid therapy. One prominent KOL sponsored by many of the Manufacturer Defendants, Dr. Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding.

215. Collegium Vice President, Steven Passik, has proudly identified Dr. Portenoy as one of his mentors, stating that Dr. Portenoy, among others, "taught me everything I know about pain and encouraged and supported me long before I had any idea of what I was talking about."[65]

216. Some KOLs have even gone on to become direct employees and executives of Manufacturer Defendants, like Dr. Haddox, Purdue's Vice President of Health Policy, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

217. Manufacturer Defendants provided substantial opportunities for KOLs to author articles or research studies on topics Manufacturer Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well under way and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

218. Manufacturer Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, often over meals or at conferences. Since 2000, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

219. Manufacturer Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said – as they did with all their recruited speakers.

220. There was a group of KOLs who received funding and benefits from all of the Manufacturer Defendants, who participated in an enterprise to pay these KOLs, to disseminate misinformation about the safety and efficacy of opioids as a treatment for chronic pain in order to enable the Manufacturer Defendants to unlawfully expand their profits.

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[65] *Pundit Profiles: Steven D. Passik, PhD*, PAINWEEK (Jan. 4, 2017), https://www.painweek.org/brainfood_post/steven-d-passik-phd.html.

221. Dr. Portenoy received research support, counseling fees, and honoraria from Manufacturer Defendants Purdue, Cephalon, Janssen, and others. He was also president of the Front Group American Pain Society ("APS") and board member of Front Group American Pain Foundation ("APF").

222. Dr. Lynn Webster was the author of numerous CMEs sponsored by Purdue, Cephalon, Endo, and Collegium. He was also president of the Front Group American Academy of Pain Medicine ("AAPM") and board member of APF. Dr. Webster also currently serves as the Scientific Advisor to Collegium.[66] In addition, Dr. Webster has disclosed receiving "honoraria, consultant fees and/or travel expenses" from Collegium, Insys, Mallinckrodt, and Cephalon.[67]

223. Dr. Scott Fishman was a KOL who authored *Responsible Opioid Prescribing*, a publication sponsored by Manufacturer Defendants Purdue and Cephalon. Dr. Fishman was also a president of APF and AAPM.

224. Dr. Perry Fine was a KOL who received funding from Manufacturer Defendants Purdue, Cephalon, Janssen, and Endo. He was also president of AAPM and board member of APF.

c. Continuing Medical Education

225. Massachusetts physicians are required to attend CMEs in order to keep their medical licenses. Manufacturer Defendants sponsored CMEs and made sure that the content supported their position on opioids. They were thereby able to promulgate their teaching to a large number of doctors that they should be prescribing more opioids.

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66 *Executive Profile: Lynn R. Webster M.D., FACPM, FASAM,* BLOOMBERG https://www.bloomberg.com/research/stocks/people/person.asp?personId=24452366&privcapId=7490189 (last visited Mar. 4, 2019).

67 Lynn R. Webster, *Opioid-Induced Constipation*, 16 PAIN MEDICINE S16 (2015), *available at* https://onlinelibrary.wiley.com/doi/full/10.1111/pme.12911.

226. Because CMEs are typically delivered by KOLs who are highly respected in their fields, and are thought to reflect these physicians' medical expertise and "cutting edge" practices, these CMEs can be especially influential to doctors.

227. The countless doctors and other healthcare professionals, who participate in accredited CMEs, constituted an enormously important audience for opioid reeducation. Manufacturer Defendants targeted general practitioners, who were especially susceptible to Manufacturer Defendants' deceptions because of their lack of specialized training in pain management and the likelihood that they would treat patients seeking medical treatment for pain management issues.

228. These CMEs, often with names related to treatment of chronic pain, inflated the benefits of opioids, omitted or downplayed their risks, and focused on opioids to the exclusion of alternative treatments.

229. The influence of Manufacturer Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times.

230. Students who read the industry-funded article noted more frequently the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CME included the risks of death and addiction much more frequently than those of the other group.

231. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty medical practitioners (the audience for CMEs) have in screening and accounting for source bias.[68]

232. By sponsoring CME programs presented by Front Groups, like AAPM, APF, and others, like PAINWeek, Manufacturer Defendants could expect messages to be favorable to them, as these organizations were financially dependent on Manufacturer Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Manufacturer Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids.

d. Treatment Guidelines

233. Manufacturer Defendants produced treatment guidelines for doctors. Such guidelines were crucial for giving legitimacy to extensive opioid prescriptions and providing a framework within which doctors would feel comfortable prescribing them. These guidelines are also cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications.

(i) Federation of State Medical Boards

234. The Federation of State Medical Boards ("FSMB") is an organization representing the various state medical boards in the United States, including the Massachusetts Board of Medicine, which have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Manufacturer Defendants.

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[68] Adriane Fugh-Berman, *Marketing Messages in Industry-Funded CME*, PHARMED OUT (June 25, 2010), http://www.pharmedout.org/pdf/Conf2010/Fugh-BermanPrescriptionforConflict6-25-10.pdf.

235. In 1998, the FSMB developed its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB conceded was produced "in collaboration with pharmaceutical companies." From 1997 to 2013, FSMB received more than $2 million from the Manufacturer Defendants (other than Insys or Collegium). The FSMB Guidelines taught that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose and discussed addiction only in the sense that "inadequate understanding" of addiction can lead to "inadequate pain control."

236. The publication of *Responsible Opioid Prescribing*, a book adapted from the FSMB Guidelines, was backed largely by Manufacturer Defendants, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors). There were 163,131 copies of *Responsible Opioid Prescribing* distributed to state medical boards, including the Massachusetts Board of Medicine (and through the boards, to practicing doctors), and the FSMB earned approximately $250,000 in revenue and commissions from their sale.

237. The FSMB Guidelines conveyed the message that "inadequate pain control" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.

238. Through the FSMB Guidelines, the Manufacturer Defendants were able to turn doctors' fear of discipline on its head – doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that instead, they would be punished if they failed to prescribe opioids to their patients with pain.

(ii) AAPM/APS Guidelines

239. AAPM and APS are professional medical societies, each of which received substantial funding from the Manufacturer Defendants from 2009 to 2013 (with AAPM receiving well over $2 million).

240. AAPM issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids for treating chronic pain and claimed that the risk of addiction to opioids was low.[69] The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue and subsequently became Vice President of Health Policy at Purdue. Dr. Portenoy, one of the main KOLs who received funding from Manufacturer Defendants Janssen, Cephalon, Endo, and Purdue, was the sole consultant. The consensus statement formed the foundation of the FSMB Guidelines. That statement was actively distributed by AAPM until 2012.

241. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines"), continuing to recommend the use of opioids to treat chronic pain.[70] Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

242. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.

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[69] The American Academy of Pain and the American Pain Society, *The Use of Opioids for the Treatment of Chronic Pain*, 13 CLINICAL J. PAIN 6 (1997), *available at* http://www.jpain.org/article/S1082-3174(97)80022-0/pdf.

[70] Roger Chou, *et al.*, *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 J. PAIN 113 (2009), *https://www.jpain.org/article/S1526-5900(08)00831-6/pdf.*

243. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the AAPM/APS Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members.

244. The AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The AAPM/APS Guidelines have been cited 732 times in academic literature, are still available online, and were reprinted in the JOURNAL OF PAIN.

245. Defendants widely referenced and promoted the AAPM/APS Guidelines without disclosing the acknowledged lack of evidence to support them.

(iii) American Geriatrics Society

246. The American Geriatrics Society ("AGS"), a nonprofit organization serving healthcare professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002, *The Management of Persistent Pain in Older Persons* (hereinafter "2002 AGS Guidelines"), and 2009, *Pharmacological Management of Persistent Pain in Older Persons* (hereinafter "2009 AGS Guidelines").

247. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy" and stated that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[71] These

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[71] B. Ferrell, *et al.*, *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. AM. GERIATR. SOC'Y 1339, 1342 (2009), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1532-5415.2009.02376.x.

recommendations are not supported by any study or any other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

248. AGS contracted with Manufacturer Defendants Endo, Purdue, and Janssen to disseminate the 2009 AGS Guidelines, and to sponsor CMEs based on them. The Manufacturer Defendants were aware of the content of the 2009 AGS Guidelines when they agreed to provide funding for these projects.

249. The 2009 AGS Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Manufacturer Defendants, including Endo and Purdue, beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that AGS did not want to receive up-front funding from Manufacturer Defendants, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the 2009 AGS Guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they had approved the message, AGS effectively ceded significant control to these companies. Endo, Janssen, and Purdue all agreed to provide support to distribute the 2009 AGS Guidelines.

250. Five of ten of the experts on the 2009 AGS Guidelines's panel disclosed financial ties to Manufacturer Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Manufacturer Defendants, receiving grants from Manufacturer Defendants, and investing in Manufacturer Defendants' stock.

251. As noted *infra* at ¶¶271-72, the recommendations (in this case, treatment guidelines) of those organizations not financed by Manufacturer Defendants stood in marked contrast to those financed by the Defendants.

e. Front Groups and Unbranded Advertising

252. Manufacturer Defendants Purdue, Endo, Janssen, Collegium, and Cephalon collectively used unbranded, third-party marketing (through KOLs and Front Groups) as part of their national marketing strategies for their branded drugs. Unbranded advertising had the dual advantage of having an appearance of independence and credibility and not being subject to the regulations promulgated by the FDA for branded advertising. The purpose of the FDA regulations on branded advertising, 21 U.S.C. §352(a) and 21 C.F.R. §§1.21(a), 202.1(e)(3), and 202.1(e)(6), is to encourage truthful advertising.

253. Defendants published print advertisements in a broad array of medical journals, ranging from those geared to a wider audience, such as the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, to those targeted more at specialists, such as the JOURNAL OF PAIN. In 2011 alone, Defendants' advertising budgets exceeded $14 million on the medical journal advertising of opioids, which was nearly three times what they spent in 2001.

254. Manufacturer Defendants Purdue, Cephalon, Janssen, Endo, and Actavis engaged in a series of actions designed to thwart federal advertising guidelines, market themselves by way of seemingly neutral third parties, and appear distanced from these organizations, while simultaneously funneling large amounts of money into them. By doing so, they were able to engage in a multi-pronged effort to misrepresent the risks and overstate the benefits of using opioids. These Manufacturer Defendants were also able to change prescribing practices through materials that appeared not to be marketing.

255. One part of this approach was to influence the stances of Front Groups by heavily contributing to the organizations' income. Manufacturer Defendants then turned around and cited materials produced by these groups as evidence of their positions.

(i) APF's Role as a Front Group for Defendants' Deceptive Marketing

256. APF was a prominent Front Group for Manufacturer Defendants. The group's name is meant to sound official and impartial, but, in fact, this organization was a front for promotional material and advocacy on behalf of the Manufacturer Defendants.

257. Between 2007 and until its closure in May 2012, APF received upwards of $10 million from Manufacturer Defendants. In 2009 and 2010, it received from them more than 80% of its operating budget. In 2010, for example, APF received more than $1 million from Endo.

258. APF issued "education guides" for patients, policymakers, and the news media that advocated the benefits opioids provided for chronic pain and trivialized their risks, particularly the risk of addiction. APF engaged in a significant multimedia campaign through television, radio, and the internet to purportedly "educate" patients about their "right" to pain treatment with opioids.

259. The publications available from APF extolled the benefits of opioids, and these publications were underwritten by Manufacturer Defendants Purdue, Cephalon, Janssen, and Endo. For example, one board member published a study in 2010 sponsored by Cephalon, finding that Cephalon's drug Fentora was "generally safe and well-tolerated" in non-cancer patients, even though it was only approved for severe cancer pain.

260. APF held itself out as an independent patient advocacy organization. In reality, APF functioned largely as an advocate for the interests of Defendants, not patients. APF engaged in grassroots lobbying efforts against various legislative initiatives that might limit opioid prescribing, exemplifying APF's true interest which was to make money for the manufacturers, and ignoring patient pain concerns.

261. In practice, APF operated in close collaboration with Manufacturer Defendants. APF submitted grant proposals seeking to fund activities and publications they suggested and assisted in marketing projects for them.

262. APF and APS submitted *amicus* briefs in defense of opioids: in one case, in support of Defendant Purdue; in another, in support of a doctor on trial for over-prescribing pain medication (who was subsequently found guilty of 16 counts of drug trafficking).

263. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others for funding, which also thereby enabled APF to avoid using its line of credit. APF board member, KOL Dr. Portenoy, explained that the lack of funding diversity was one of the biggest problems at APF.

264. All of APF's programs and materials were intended to, and did, reach a national audience, including persons within the Town of Randolph.

265. A 2012 U.S. Senate Finance Committee investigation between manufacturers and APF resulted in an abrupt halt to this funding. APF's board of directors dissolved the group within days of this investigation.

(ii) The Role of Other Front Groups in Defendants' Deceptive Marketing

266. AAPM similarly has received more than $2 million from opioid manufacturers since 2009. This group issues treatment guidelines and hosts CME courses, while espousing positions consistent with opioid manufacturers. Presidents of this organization include many of the KOLs mentioned above. A yearly meeting put on by AAPM allows the group to interface with opioid manufacturers, who pay to present "medical education programs" to AAPM and attending doctors.

267. Other Front Groups include the University of Wisconsin Pain & Policy Studies Group, which received $2.5 million from opioid manufacturers to lobby and otherwise promote opioid use; and APS, incorporated in 1977, whose primary corporate supporter is pharmaceutical manufacturer Mallinckrodt. Similarly, the Pain Care Forum, a Front Group sponsored by Collegium, comprises a group of over 100 drug manufacturers and advocacy groups that coordinates efforts to influence legislation concerning prescription pain medications on both federal and state levels. The following chart shows the top 20 states with the highest number of registered Pain Care Forum lobbyists:[72]

Registered lobbyists for members of Pain Care Forum in each state
2006-2015

STATE	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	AVERAGE	RANK*
PA	116	110	104	90	90	82	82	45	36	67	82	1
NH	11	15	22	23	23	23	21	21	19	22	20	2
ME	8	8	17	16	17	17	21	20	14	10	15	3
LA	52	50	55	26	54	57	20	32	26	32	40	4
NJ	69	75	73	59	15	15	21	78	83	95	58	5
CO	21	18	16	18	35	35	73	32	40	36	32	6
CT	33	41	49	44	56	49	50	50	54	51	48	7
CA	40	59	59	8	45	82	69	79	85	104	63	8
VT		20	20	21	24	17	26	16	29		22	9
WV	24	21	21	19	20	13	16	17	17	15	18	10
MD	26	25	30	17	29	32	40	37	34	43	31	11
SC	20	16	16	20	20	20	16	12	12	12	16	12
IA	21	25	38	46	31	24	33	37	32	41	33	13
MA	37	38	40	38	69	82	21	23	23	74	45	14
TN	25	24	23	18	18	17	22	21	23	21	21	15
MS	16	17	21	24	19	21	17	18	10	15	18	16
ID	13	10	13	17	19	16	15	15	17	25	16	17
AK	3	7	10	6	5	6	5	6	6	4	6	18
TX	47	69	61	63	71	64	71	78	63	63	65	19
HI	8	9	13	11	10	12	11	14	14	9	11	20

72 Eugene Tauber, *Lobbyists Hired by Advocates for Opioid Manufacturers in Every State*, THE MORNING CALL (Sept. 17, 2016), http://www.mcall.com/news/local/data/mc-politics-of-pain-state-lobbyists-htmlstory.html.

268. As of 2015, Massachusetts was one of the top states being targeted by the Pain Care Forum's lobbying efforts. In fact, from 2014 to 2015, the Pain Care Forum tripled the number of lobbyists it had advocating for Defendants in the Commonwealth of Massachusetts from 23 to 74, respectively.

269. These Front Groups provided important services for the Manufacturer Defendants. They prepared and disseminated unbranded materials promoting the use of opioids to doctors and the public, including by conducting CMEs and issuing treatment guidelines for doctors, and by outreach targeting particularly vulnerable groups, such as veterans and elderly people. They also advocated against regulatory guidelines that would limit opioid prescriptions, and responded negatively to journal articles not supporting the use of opioids. The significant funding and regular interfacing between these sets of organizations ensured that the Front Groups would issue messages supporting the position(s) of the opioid manufacturers.

270. Defendants Purdue, Endo, Janssen, Cephalon, and Actavis collectively exercised substantial control over the content of the messages third parties generated and disseminated and distributed certain of those materials themselves. These Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by these third parties, ensuring that Manufacturer Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Manufacturer Defendants exercised control over their deceptive messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

271. The behavior and positions of those groups that did not accept funding from manufacturers contrasts significantly with that of the Front Groups. The American Society of Interventional Pain Physicians only recommends high doses of long-acting opioids "in specific

circumstances with severe intractable pain" along with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[73]

272. The American College of Occupational and Environmental Medicine similarly discourages "routine use of opioids in the management of patients with chronic pain," though conceding that for some patients it may be appropriate.[74] The U.S. Department of Veteran Affairs ("VA") and the U.S. Department of Defense ("DoD") note risks of abuse and misuse, and "the lack of solid evidence based research on the efficacy of long-term opioid therapy."[75]

f. Defendants Inappropriately Used Their Sales Force and "Speakers Bureaus" to Unfairly and Deceptively Promote Use of Their Drugs

273. Like most drug manufacturers, the Manufacturer Defendants made extensive use of their sales force – sometimes called "detailers" – to meet with physician groups one-on-one and promote their products through intimate settings, with promotions being advanced by paid speakers. The degree to which the Defendants organized their sales force to "lock-step" sell their products, based on falsehoods and material omissions, is what rendered their marketing efforts unlawful.

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[73] Bradley W. Wargo, *et al.*, *Am. Soc'y Interventional Pain Physicians (ASIPP), Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain* (pts. 1 & 2), 15 PAIN PHYSICIAN S1, S67 (2012), *available at* https://www.ncbi.nlm.nih.gov/pubmed/22786448 & https://www.ncbi.nlm.nih.gov/pubmed/22786449.

[74] *ACOEM's Guidelines for the Chronic Use of Opioids*, AM. C. OF OCCUPATIONAL & ENVTL. MED. (2011), https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf.

[75] The Management of Opioid Therapy for Chronic Pain Working Group, *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, U.S. DEP'T OF VETERANS AFFAIRS (May 2010), https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf.

274. Defendants' marketing plans, which often operated in parallel to one another, targeted physician groups far afield from pain specialists and anesthesiologists (or cancer doctors) to include physician groups, such as general practice physicians, sports medicine physician groups, etc., with no correlation to the demonstrated needs of the physicians' patients for opioid therapy, or to the risk of abuse.

275. The expanded market of prescribers tended to be, as a group, less informed about opioids and more susceptible to Defendants' marketing. The prescribers included nurse practitioners and physician assistants considered to be "share acquisition" opportunities because they were "3x more responsive than MDs to detail," according to an Endo business plan.

276. The expanded market also included internists and general practitioners, with a stated goal, for example, according to an Actavis plan, to move beyond "Kadian loyalists" to an "expanded audience" of "low morphine writers."

277. Each Manufacturer Defendant relied upon "influence mapping," which meant using decile ranking identifying high-volume prescribers, so that the manufacturer's sales force would get the biggest impact from sales calls. Defendants also closely monitored a doctor's prescribing after a sales representative's visit to allow them to fine-tune their messaging.

278. Each Defendant studiously trained its sales representatives – through detailed action plans, trainings, tests, scripts, role-plays, and supervision tag-alongs – to ensure that the individual sales representatives stayed strictly on script, which involved selling their opioids for off-label uses.

279. Purdue rewarded its high-prescribing doctors, and rewarded them well. Purdue showered these doctors with attention, meals, gifts, and money. Purdue has given money, meals, or gifts to more than 2,000 individual Massachusetts prescribers since May 15, 2007.

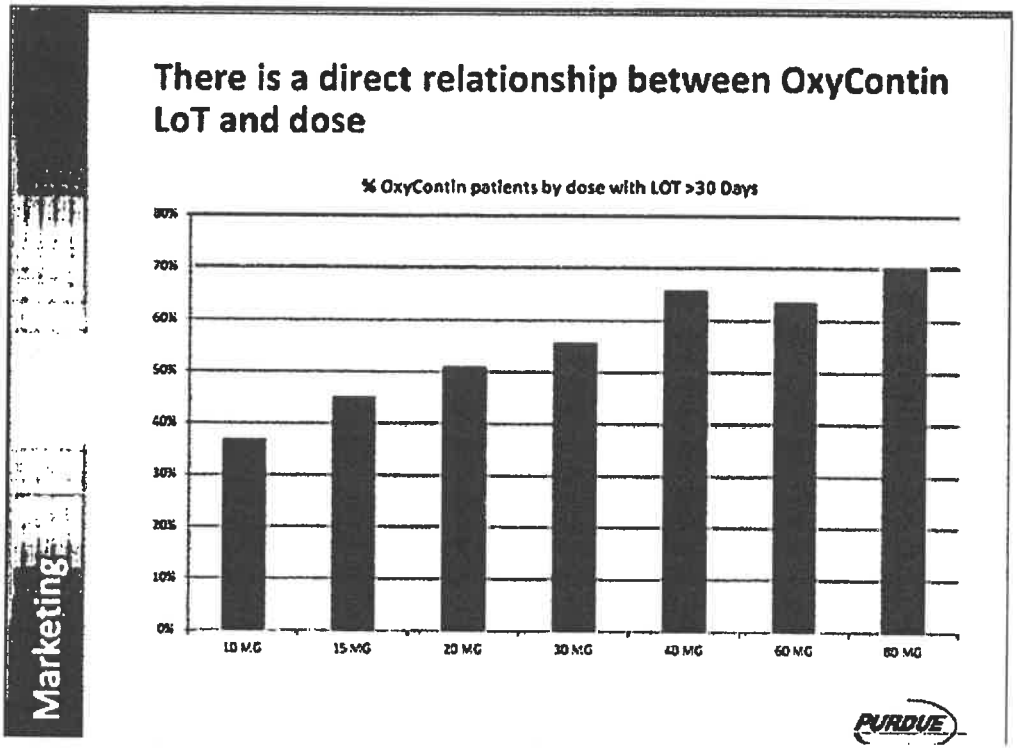
280. In addition to the sales calls, sales representatives were required to identify "product loyalists" – who were high prescribers of drugs – to be selected to be speakers on behalf of the Manufacturer Defendants and invited to give speeches to their peers proclaiming the effectiveness of the respective manufacturer's opioid. The speakers were paid handsomely for this service with honoraria ranging from about $800 to $2,000 per program.

281. The Manufacturer Defendants all tracked the effectiveness of the speakers program by monitoring the prescription writing of the attending physicians after the speaker program. It was an effective strategy. Endo noted that "physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than before."

282. Defendants devoted substantial resources to these direct sales contacts with prescribers. In 2014, Defendants collectively spent $168 million on detailing branded opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The total figure is more than double Defendants' collective spending on detailing in 2000. Detailers' role in Defendants' overall promotional efforts was also carefully calibrated; Endo, for example, found that devoting 61% of its marketing budget to sales representatives reflected an "[a]ppropriate combination of personal . . . and non-personal . . . selling initiatives."

283. Defendants spent hundreds of millions of dollars promoting their opioids through their large sales forces because their monitoring showed that the sales forces' face-to-face meetings with prescribers had a significant influence on prescribing rates. As a routine matter, the Defendants incentivized their sales representatives to sell by basing their compensation on a low salary/high commission format.

284. Upon information and belief, Purdue gave its salespeople explicit instructions to "extend average treatment duration." Purdue's business plans valued patients by how long they could be kept on Purdue's opioids. Purdue developed tactics specifically to keep patients hooked on opioids longer, which it called by the euphemism: *Improving the Length Of Therapy* – sometimes abbreviated as "LOT" or "LoT." Purdue taught its employees that there is "a direct relationship" between getting patients on higher doses and keeping them on Purdue's opioids longer. Purdue's internal marketing plan showed a graph that broke down exactly how getting patients on higher doses of opioids would get more patients to stay on drugs longer:



Purdue internal strategy presentation from 2012.

285. Upon information and belief, hundreds or thousands of visits from sales representatives from each of the Manufacturer Defendants were made to prescribers in Randolph and the surrounding area, where the message regarding the use and safety of opioid therapy for the prescribers' patients was untethered from any scientific basis, as the Defendants well knew.

286. A national study of tens of thousands of medical and pharmacy claims records published in the JOURNAL OF GENERAL INTERNAL MEDICINE found that two-thirds of patients who took opioids for 90 days were still taking opioids ***five years later***.

287. Collegium is continuing the practice of sending sales representatives or detailers directly to physicians' offices to increase sales, despite the practice being severely criticized. For example, Collegium's March 2018 Form 10-K states, as follows:

> We have a dedicated field sales force, consisting of approximately 131 sales professionals, to call on the approximately 11,000 physicians who write approximately 58% of the branded extended-release oral opioid prescriptions in the United States, with a primary focus on pain specialists. In addition, we deploy a focused sales force of approximately 14 specialty sales representatives to call on hospitals."[76]

The sales force, therefore, constitutes more than half of Collegium's full time staff.

288. Upon information and belief, members of those sales force personnel are marketing the use of Xtampza ER, Nucynta and Nucynta ER to physicians, and nurse practitioners with prescription-writing authority, within Randolph and its surrounding area, and are falsely representing that their opioid products Xtampza ER, Nucynta and Nucynta ER should be used even where safer methods of pain relief have not been tried and failed. Collegium escalated its use of detailers while other opioid manufacturers have finally disavowed this discredited practice.

289. Upon information and belief, Collegium is now responsible for a significant amount of the detailing of prescribers by opioid manufacturers in the Randolph area.

290. In a lawsuit initiated in Norfolk Superior Court, LeighAnne Pendlebury, a discharged salesperson referred to as a "Therapeutic Specialist" for Collegium, alleged that she,

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[76] Collegium Annual Report, *supra* n.60, at 15.

and other sales representatives, was directly ordered by her supervisors at Collegium, upon orders from Michael Heffernan, Collegium's CEO and President, to:

(a) use marketing materials in their sales visits to prescribers that had ***not*** been approved by the FDA;

(b) end all sales pitches to providers by having the sales representatives cross their arms in the shape of an "X" and say "Xtampza crosses out tampering," even though the FDA warned Collegium that use of the term "tamper-proof" was misleading because the drug was not tamper-proof; and

(c) fabricate phony doctors' names on attendance sheets for Collegium's dinner programs as a way of covering up excessive payments to targeted physicians for expensive (over $10,000) meals.

291. Collegium is also utilizing the discredited method of relying on KOLs to market the use of its opioid. Its March 2018 Form 10-K states, as follows:

> We are continuing to execute our commercialization strategy with the input of key opinion leaders in the field of pain management, as well as healthcare practitioners. We have developed positioning and messaging campaigns, a publication strategy, initiatives with payor organizations, and distribution and national accounts strategies. Our marketing strategy includes increasing awareness of the differentiated features of Xtampza and the Nucynta Products and increasing awareness of solutions for patients with CPD [Chronic Pain Disorder] who require or would benefit from extended-release opioids.[77]

g. Direct-to-Consumer Marketing

292. Manufacturer Defendants targeted patients so that they would ask doctors for those medications specifically. Endo's research, for example, found that such direct-to-consumer communications resulted in greater patient "brand loyalty," with longer durations of Opana ER

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77 *Id.*

therapy and fewer discontinuations. Patient-focused advertising, especially direct-to-consumer marketing, is seen by marketing experts within the pharmaceutical industry as substantially valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[78] An Actavis marketing plan, for example, noted that "[d]irect-to-consumer marketing affects prescribing decisions."

293. Defendants marketed to consumers through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physicians' offices. Endo also targeted employer and workers' compensation plan initiatives. This marketing was intended to, and did, result in patients requesting opioids in reliance on Defendants' statements that contained falsehoods and material omissions.

294. Defendants also recognized the obstacle that out-of-pocket costs to patients posed to their bottom line sales figures. They overcame this obstacle by providing patients financial assistance with their insurance co-payments through vouchers and coupons distributed by Defendants' sales representatives when they visited prescribers. For example, in 2012, Janssen planned to distribute 1.5 million savings cards worth $25 each.

295. Defendant Insys brought the effort to get insurance to pay for its product to an entirely new level of fraud. As the *Fueling an Epidemic* Senate report describes, Insys created a separate department, the Insys Reimbursement Center ("IRC"), that was designed to obtain quick approvals for insurance reimbursement for Insys's product, Subsys, which is an orally administered spray of fentanyl. The IRC unit exercised fraud and deception (such as pretending to be calling from a physician's office and falsely representing that the prescription was for a

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[78] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 ALBANY L. REV. 299, 308 (2013).

cancer patient, which was the only FDA-approved indication for Subsys). The head of the IRC unit, Elizabeth Guerrieri, pled guilty to "having conspired to defraud insurers" (wire fraud) in June 2017 in the U.S. District Court for the District of Massachusetts.

(i) The Elderly

296. Defendants have promoted the unfounded notion that the elderly are particularly unlikely to become addicted to opioids. The 2009 AGS Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse." There is not now, nor has there ever been, any scientifically based evidence to support this statement.

297. On the contrary, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.[79]

298. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, greater risk for hospitalizations, increased vulnerability to adverse drug effects and interactions, such as respiratory depression, and a significantly higher rate of deaths, heart attacks, and strokes than users of NSAIDs.

299. Defendants' targeted marketing to the elderly, and the absence of cautionary language in their promotional materials flies in the face of scientific evidence, their own labels, and creates a heightened risk of serious injury to elderly patients.

300. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

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[79] Kate M. Dunn, *et al.*, *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152 ANNALS INTERNAL MED. 85 (2010), *available at* http://annals.org/aim/article-abstract/745518/opioid-prescriptions-chronic-pain-overdose-cohort-study.

301. Upon information and belief, a Purdue supervisor in Massachusetts coached sales representatives to "Keep the focus on the geriatric patients" and follow Purdue's "geriatric strategy." Purdue trained its representatives to show doctors charts emphasizing Medicare coverage for its opioids, and use profiles of fake elderly patients in chronic pain, complete with staged photographs, to convince doctors to prescribe its drugs.

302. Manufacturing Defendants saw the opportunity to earn millions of dollars by getting elderly patients on opioids because the public would pay through Medicare. Manufacturing Defendants disregarded and obscured the risks to the health of elderly patients in its deceptive sales campaign.

(ii) Veterans

303. Veterans, too, were specifically targeted for Defendants' misleading marketing. A 2008 survey showed that prescription drug abuse among military personnel had doubled from 2002 to 2005, and then nearly tripled again over the next three years.[80]

304. Compared to non-veterans, Massachusetts veterans are three times more likely to die from opioid overdose.

305. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills – four times as many as they had written in 2001. Further, one-third of veterans who were prescribed opioids, as of 2012, remained on take-home opioids for more than 90 days. Although many of

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[80] RTI INTERNATIONAL, 2008 DEPARTMENT OF DEFENSE SURVEY OF HEALTH RELATED BEHAVIORS AMONG ACTIVE DUTY MILITARY PERSONNEL (2009), https://prhome.defense.gov/Portals/52/Documents/RFM/Readiness/DDRP/docs/2009.09%202008%20DoD%20Survey%20of%20Health%20Related%20Behaviors%20Among%20Active%20Duty%20Military%20Personnel.pdf.

these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment.

306. Among former service members receiving VA services nationally, in a single year (2005), 1,013 died of an accidental drug overdose – almost double the rate of the civilian population (19.85 people out of 100,000 per year vs. 10.49 people out of 100,000 per year).[81]

307. Opioids are particularly dangerous to veterans. According to a study published in the 2013 JOURNAL OF AMERICAN MEDICINE, veterans returning from Iraq and Afghanistan, who were prescribed opioids, have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries; 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death.

308. According to a VA Office of Inspector General report, despite the risks, 92.6% of veterans prescribed opioid drugs were also prescribed benzodiazepines.[82]

309. As with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids pose to them.

310. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, and written as if it were a personal narrative of one veteran,

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81 Amy S.B. Bohnert, *et al.*, *Accidental Poisoning Mortality Among Patients in the Department of Veterans Affairs Health System*, 49 MED. CARE 393 (2011), *available at* https://journals.lww.com/lww-medicalcare/Abstract/2011/04000/Accidental_Poisoning_Mortality_Among_Patients_in.11.aspx.

82 U.S. DEP'T OF VETERANS AFF., OFF. OF INSPECTOR GEN., REP. NO. 14-00895-163, HEALTHCARE INSPECTION – VA PATTERNS OF DISPENSING TAKE-HOME OPIOIDS AND MONITORING PATIENTS ON OPIOID THERAPY (2014), https://www.va.gov/oig/pubs/vaoig-14-00895-163.pdf.

describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury.

311. *Exit Wounds* notes that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."

312. The publication also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards." As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

313. *Exit Wounds* minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which were taken by a significant number of veterans.[83] The deceptive nature of *Exit Wounds* is obvious when compared to guidance on opioids published by the VA and DoD in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects, and death – none of which is mentioned in *Exit Wounds*.

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[83] FDA draft guidance states that materials designed to target a particular audience should disclose risks particular to that audience. *See* U.S. FOOD & DRUG ASS'N, BRIEF SUMMARY AND ADEQUATE DIRECTIONS FOR USE: DISCLOSING RISK INFORMATION IN CONSUMER-DIRECTED PRINT ADVERTISEMENTS AND PROMOTIONAL LABELING FOR PRESCRIPTION DRUGS (2015), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm069984.pdf.

314. Approximately 1,440 U.S. veterans resided in the Town of Randolph, according to the U.S. Census Bureau data from 2013-2017, and, upon information and belief, many of these veterans were wrongfully prescribed opioids and received misinformation about their usefulness and safety by reading *Exit Wounds* and other means of public dissemination of misinformation promulgated by Defendants.

4. Purdue-Specific Misrepresentation: The 12-Hour Dosing Lie

315. In the late 1980s, Purdue (a relatively small pharmaceutical company at the time) was facing a serious revenue threat. Its main drug was a morphine pill for cancer patients with the trade name MS Contin. The patent on MS Contin was about to expire, which meant the drug would face serious downward pricing pressure from generics that were likely to enter the market of an opioid treatment for cancer patients.

316. To solve its "vulnerability of the . . . generic threat," Defendant Purdue decided to devote a huge effort and funding into the launch of another opioid product that it tradenamed OxyContin. OxyContin was classified as an oxycodone similar to Percocet (that was already on the market), but Purdue combined the oxycodone with a time release technique and claimed that the new drug, OxyContin, would control pain for up to 12 hours.

317. Purdue's claim that its opioid could provide 12 hours of pain relief was a primary selling point for the new drug, OxyContin. In its 1992 submission to the U.S. Patent Office, Purdue touted that OxyContin was a medical breakthrough that controlled pain for 12 hours "in approximately 90% of patients."

318. Armed with its new product, Purdue launched OxyContin in 1996 after obtaining FDA approval in 1995. A Purdue marketing executive stated in a 1995 internal memo (that was obtained by the *Los Angeles Times* and reported on in a May 5, 2016 exposé), "[w]e do not want to niche OxyContin just for cancer pain."

319. However, the promise of 12-hour pain relief was not true, which Purdue knew. The effects of OxyContin (both the pain relief and the euphoria) wore off for most of the patients in Purdue's clinical trials well before 12 hours. Many patients would start to crave another dose within eight hours, or even less time.

320. OxyContin tablets provide an initial absorption of approximately 40% of the active medical. This fact causes two results, both of which made OxyContin particularly addictive. First, the initial rush of almost half of the powerful opioid triggers a powerful psychological response. Thus, OxyContin – which is approximately twice as powerful as morphine – acts more like an immediate-release opioid. Second, since there is less of the drug at the end of the 12-hour dosing periods, many patients begin to experience withdrawal symptoms before the 12 hours expire. The combination of fast onset and end-of-dose withdrawal symptoms makes OxyContin powerfully addictive.

321. Although Purdue was well aware of the shorter duration of the drug's effects for many patients, it withheld this information from prescribing physicians and, to the contrary, instructed its sales force (which had ballooned to over 200 by 1997, one year after launch), to recommend to the prescribers that they increase the strength of the dose rather than its frequency.

322. By use of this falsehood, Purdue kept its competitive advantage of being able to claim that OxyContin gives a full 12 hours of relief, allowing the convenience of twice-a-day dosing.

323. This strategy was a triple win for Purdue. First, the maximum strength 80 mg of OxyContin netted Purdue more than $630, rather than the $97 for a 10 mg bottle. Second, if the patient, in the throes of opioid withdrawal, started to take the drug at shorter intervals, Purdue

could claim it was "not their problem." Third, the increased dose made the drug even more addictive, thereby making it likely that Purdue would have a customer for life.

324. To this day, Purdue continues to misrepresent OxyContin to doctors as a 12-hour drug.[84]

325. The *Los Angeles Times* exposé stated that, as of 2014, more than 52% of patients taking OxyContin longer than three months were prescribed doses greater than 60 mg per day. Dr. Debra Houry of the CDC stated in 2017 that those doses were "really concerning" because "the higher you go, the more likely you are to die."

5. Insys-Specific Misrepresentation

326. Insys is one of the last entrant into the prescription opioid market among the Manufacturer Defendants, having acquired FDA approval for its drug, tradenamed Subsys, in 2012.

327. As discussed *supra* at ¶81, Subsys is a highly addictive synthetic opioid form of fentanyl mouth-spray approved by the FDA for a very limited indication: treatment of breakthrough cancer pain only in patients who have already been administered other opioids, so they have established a tolerance for opioids.

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[84] *OxyContin® CII (Oxycodone HCI) Extended- Release Tablets*, PURDUE PHARMA, http://www.purduepharma.com/healthcare-professionals/products/oxycontin (last visited Mar. 4, 2019); *OxyContin®: Highlights of Prescribing Information*, PURDUE PHARMA (Dec. 2016), http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o (OxyContin prescription information); *Medication Guide: OXYCONTIN® (ox-e-KON-tin)(oxycodone hydrochloride) extended-release tablets, CII, PURDUE PHARMA* (Dec. 2016), http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o&medguide=1 (medication guide); *Setting The Record Straight On Oxycontin's FDA-Approved Label*, PURDUE PHARMA (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label (responding to the Los Angeles Times article by doubling down on its claims).

328. Insys has mounted an aggressive and unlawful off-label marketing strategy for Subsys in violation of the FDCA, 21 U.S.C. §301, *et seq.*, knowingly marketing its product for uses that were not approved by the FDA, which led to the submission of false and improper payment requests to government programs Medicare and Medicaid and indictments and/or pleas of many of its key executives.

329. There is a limited customer base for cancer patients who are already taking an opioid to manage cancer pain, but still need an additional boost to treat breakthrough cancer pain. Accordingly, Insys determined to sell its potent and dangerous opioid to a wider class of patients. Their sales force, whose pay was largely dependent on commissions, visited dentists, chiropractors, general practitioners, and others throughout the country, including in Massachusetts, the Town of Randolph, and surrounding area, to market Subsys for a wide variety of ailments, from root canals to back pain.

330. The Senate report, *Fueling an Epidemic*, revealed, among other things, how the Insys sales force was incentivized and indoctrinated to sell Subsys as a safe treatment for many conditions far afield from breakthrough cancer pain. Moreover – and just as dangerously – the sales staff was instructed to induce their physicians to write prescriptions for higher, more expensive doses.

331. Manufacturer Defendant Insys, and Individual Defendant Kapoor, knew that the off-label use of Subsys could be fatal, and, at the very least, could lead to addiction in the user. Despite this knowledge, Manufacturer Defendant Insys unlawfully, recklessly, and with wanton, willful, and criminal intent continued to market its product for the use of innocent persons for whom it was foreseeable that it would cause grave and perhaps fatal harm.

332. On December 16, 2016, the U.S. Attorney for the District of Massachusetts announced the indictment of six former Insys executives and managers on a host of charges stemming from "a nationwide conspiracy to profit by using bribes and fraud to cause the illegal distribution of a Fentanyl spray [i.e. Subsys] intended for cancer patients experiencing breakthrough pain." On October 24, 2017, a superseding indictment named and incorporated Individual Defendant Kapoor for his role in that conspiracy. On November 28, 2019, the former head of sales for Insys, Alec Burlakoff, pled guilty to racketeering conspiracy. On January 9, 2019, the company's President and CEO, Michael Babich, also pled guilty to racketeering conspiracy. Individual Defendant Kapoor's trial began on January 28, 2019.

333. Notably, according to the indictment filed in *U.S. v. Babich*, five of the former Insys executives organized speaker events for medical practitioners at high-priced restaurants in Massachusetts, which were, in truth, "often just social gatherings . . . that involved no education and no presentation." These sham speaker program events "functioned as bribes in the form of free dinners with friends." In return for these bribes, the medical practitioners "were expected to prescribe [Subsys] to their patients."

6. Actavis-Specific Misrepresentation

334. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and mental health," and cause patients to enjoy their lives. The FDA warned Actavis that such claims were misleading, disclaiming: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive

impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[85]

335. Actavis disregarded the FDA's 2010 warning and Actavis sales representatives continued to market the falsehood that prescribing Actavis's opioids would improve patients' ability to function and improve their quality of life.

336. Actavis's sale training modules severely downplayed the association of Kadian and other opioids as to the risk of addiction. A 2010 module represented that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction," and instead, "[i]t appears likely that most substance-abusing patients in pain management practices have an abuse problem before entering the practice." Not only did Actavis falsely suggest the low likelihood of addiction in patients, but also shifted culpability to the patients, the same people they were entrusted to treat.

7. The Sackler Family Defendants Control and Direct Purdue's Misconduct

337. Purdue's misconduct has been directed and encouraged by its own board of directors. This small group of people controlled Purdue and sanctioned the unlawful conduct perpetrated by those companies.

338. The directors control both Purdue Pharma Inc. and Purdue Pharma L.P. and run the companies as their personal enterprise.

339. Richard Sackler, Jonathan Sackler, Beverly Sackler, Theresa Sackler, Mortimer D.A. Sackler, Kathe Sackler, Ilene Sackler Lefcourt, and David Sackler hold seats on the Board of

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[85] Letter from Thomas Abrams, Dir., Div. of Mktg., Adver., & Commc'ns, FDA, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (available at https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf) ("Warning Letter").

Directors of Purdue Pharma Inc. Their family owns the company. Richard, Jonathan, Beverly, Theresa, Mortimer, Kathe, and Ilene have been on the board since the 1990s. David has been on the board since 2012.

340. Richard Sackler was as an inventor of the original patent for OxyContin. He testified that the family has made more than $1 billion from OxyContin alone.

341. Each of the Sackler Family Defendants had an obligation, which they violated, to manage Purdue in a lawful manner, rather than allow it to engage in widespread wrongdoing.

342. Upon information and belief, the Sackler Family Defendants are intimately involved in the activities of Purdue Pharma Inc. and Purdue Pharma L.P.

343. Upon information and belief, as members of the Purdue board of directors the Sackler Family Defendants directed Purdue's sales representatives to make visits to doctors in and around Randolph to implement a deceptive marketing scheme that killed Randolph residents and burdened the community's resources.

344. Upon information and belief, as members of the Purdue board of directors the Sackler Family Defendants directed payments to Massachusetts doctors—including doctors in the Randolph area—to promote Purdue's drugs.

345. Upon information and belief, as members of the Purdue board of directors the Sackler Family Defendants directed Purdue to deceive doctors and patients about its opioids and to continue promoting opioids to target doctors even after it found evidence of improper prescribing by those doctors.

346. This misconduct caused injury in Randolph by, among other things, killing its residents, burdening public services, and causing the deterioration of its public spaces.

8. Guilty Pleas and Prior Attorney General Settlements with Certain Defendants in Connection with Improper Opioid Marketing

a. Purdue's 2007 Guilty Plea for OxyContin Marketing Misrepresentations

347. In 2007, Purdue and three top executives were indicted in federal court in Virginia and pled guilty to fraud in promoting OxyContin as non-addictive and appropriate for chronic pain.

348. As part of its guilty plea, Purdue admitted that:

> Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:
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> * * *
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> b. [Purdue] told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;
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> c. [Purdue] sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;
>
> d. [Purdue] told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
>
> e. [Purdue] told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[86]

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[86] Agreed Statement of Facts at ¶20, *United States v. Purdue Frederick Co., Inc.*, No. 1:07-CR-29 (W.D. Va. May 10, 2007), ECF No. 5-2.

349. Under the plea agreement, Purdue agreed to pay $600 million in criminal and civil penalties – one of the largest settlements in history for a drug company's marketing misconduct.[87] Also, Purdue's CEO, General Counsel, and Chief Medical Officer pled guilty and agreed to pay a total of $34.5 million in penalties.[88]

350. Even after this plea, Purdue's wrongdoing continued, including its improper marketing campaign, which, along with the other Manufacturer Defendants, conditioned physicians to believe that opioids were safe and effective treatments for the long-term treatment of chronic pain.

351. Purdue made many subsequent misleading statements regarding its own opioid products and opioids generally, continuing long after its 2007 guilty plea as alleged herein.

b. Cephalon Enters a Criminal Plea for Off-Label Marketing of Actiq.

352. The FDA approved the powerful fentanyl drug, Actiq, in the form of a lollipop for use only in opioid-tolerant cancer patients (meaning those patients for whom morphine-based painkillers were no longer effective).

353. From 2001 through at least 2006, Cephalon, the manufacturer of Actiq, promoted the drug for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, and injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not opioid-tolerant and for whom the drug could be fatal.

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87 Plea Agreement, *United States v. Purdue Frederick Co., Inc.*, No. 1:07-CR-29 (W.D. Va. May 10, 2007), ECF No. 6

88 Plea Agreements, *United States v. Purdue Frederick Co., Inc.*, No. 1:07-CR-29 (W.D. Va. May 10, 2007), ECF Nos. 7-9.

354. Using the mantra "pain is pain," Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many ordinary types of pain.

355. Cephalon was charged in a criminal violation with off-label selling of Actiq, and two of its other drugs, by the U.S. Attorney for the Eastern District of Pennsylvania. In a plea agreement with the United States, entered into in September 2008, Cephalon agreed to pay $50 million in settlement of the off-label marketing charges and, in a separate civil agreement, it agreed to pay $375 million plus interest to resolve False Claims Act charges arising from the off-label selling.

356. Acting U.S. Attorney Laurie Magid stated:

> These are potentially harmful drugs that were being peddled as if they were, in the case of Actiq, actual lollipops instead of a potent pain medication intended for a specific class of patients. . . . This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.[89]

c. Purdue's 2015 Settlement with the New York Attorney General

357. On August 19, 2015, the New York Attorney General ("NYAG") entered into a settlement agreement with Purdue regarding Purdue's marketing of opioids.

358. In the settlement agreement, the NYAG noted that, from at least March 2014 to March 2015, the Purdue website, www.inthefaceofpain.com, failed to disclose that doctors who provided testimonials on the site were paid by Purdue. The NYAG concluded that Purdue's failure

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[89] Press Release, U.S. DOJ, Biopharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing (Sept. 29, 2008) (available at https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html).

to disclose these financial connections misled consumers regarding the objectivity of the testimonials.

359. The settlement agreement stated, in relevant part:

> Purdue maintains an unbranded pain management advocacy website, www.inthefaceofpain.com. From March 2014 to March 2015, the website received a total of 251,648 page views. Much of the video content on www.inthefaceofpain.com is also available on YouTube. . . .
>
> Written and video testimonials from several dozen "Advocates," whose faces appear on the website and many of whom are HCPs [health care providers], comprise a central component of the site. For example, Dr. Russell Portenoy, the recipient of almost $4,000 from Purdue for meeting and travel costs, was quoted on the website as follows: "The negative impact of unrelieved pain on the lives of individuals and their families, on the healthcare system, and on society at large is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern. Although there have been substantive improvements during the past several decades, the problem remains profound and change will require enormous efforts at many levels. Pressure from patients and the larger public is a key element in creating momentum for change."
>
> Although Purdue created the content on www.inthefaceofpain.com . . . the site creates the impression that it is neutral and unbiased.
>
> ***Purdue's failure to disclose its financial connections with certain Advocates has the potential to mislead consumers by failing to disclose the potential bias of these individuals.***[90]

[Emphasis added].

360. As part of the settlement, Purdue agreed to make certain disclosures on www.inthefaceofpain.com, and its similar websites, and to pay a monetary penalty.[91]

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[90] Assurance of Discontinuance at 8, In re. Purdue Pharma L.P. (signed Aug. 19, 2015) (No. 15-151), http://www.ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf ("NYAG-Purdue Settlement Agreement").

[91] *Id.* at 15-17.

361. Again, however, Purdue's improper marketing of opioids has continued, following its prior regulatory settlements, all as alleged more fully herein. An October 30, 2017 article in *The New Yorker* states, in pertinent part:

> Purdue has continued to fight aggressively against any measures that might limit the distribution of OxyContin, in a way that calls to mind the gun lobby's resistance to firearm regulations. Confronted with the prospect of modest, commonsense measures that might in any way impinge on the prescribing of painkillers, Purdue and its various allies have responded with alarm, suggesting that such steps will deny law-abiding pain patients access to medicine they desperately need. Mark Sullivan, a psychiatrist at the University of Washington, distilled the argument of Purdue: "Our product isn't dangerous – it's *people* who are dangerous."[92]

[Emphasis in original].

362. Further, according to that article, Purdue has continued to search for new users through the present, both domestically and now increasingly overseas, and in August 2015, even sought to market OxyContin to children as young as 11.[93]

d. Endo's 2016 Settlement with the New York Attorney General

363. On March 1, 2016, the NYAG entered into a settlement agreement with Endo regarding its marketing and sales of Opana ER.

364. On Endo's website, www.opana.com, Endo claimed, until at least April 2012, that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[94] The NYAG found that Endo had no evidence for that statement.

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92 Patrick Radden Keefe, *The Family That Built an Empire of Pain*, NEW YORKER (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

93 *Id.*

94 Assurance of Discontinuance at 6, In re. Endo Health Solutions Inc. (Mar. 1, 2016) (No. 15-228, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf ("NYAG-Endo Settlement Agreement").

365. Endo also provided training materials to its sales representatives stating that addiction to opioids is not common and "symptoms of withdrawal do not indicate addiction." The NYAG found that those statements were unwarranted.

366. Endo also trained its sales representatives to distinguish addiction from "pseudoaddiction." ***The NYAG found that "the 'pseudoaddiction' concept has never been empirically validated*** and in fact has been abandoned by some of its proponents," all as alleged above.[95] [Emphasis added].

367. The NYAG also noted that Endo omitted information about certain studies in its marketing pamphlets distributed to health care providers, and that Endo "omitted . . . adverse events from marketing pamphlets."[96]

368. As part of the NYAG settlement, Endo paid a $200,000 penalty and agreed to refrain from doing the following in New York: (i) "make statements that Opana ER or opioids generally are non-addictive"; (ii) "make statements that most patients who take opioids do not become addicted"; and (iii) "use the term 'pseudoaddiction' in any training or marketing."[97]

e. Mallinckrodt's 2017 Settlement with the DEA and U.S. Attorneys

369. In 2008, the DEA and federal prosecutors launched an investigation into Mallinckrodt, charging that the company ignored red flags by continuing to supply and failing to report suspicious orders for its generic oxycodone between 2008 and 2012.[98] The investigation

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95 *Id.* at 7.

96 *Id.* at 9.

97 *Id.* at 15, 23.

98 Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, WASH. POST (Apr. 2, 2017),

uncovered that, from 2008 to 2012, Mallinckrodt sent, for example, 500 million tablets of oxycodone into a single state, Florida – "66 percent of all oxycodone sold in the state."[99]

370. Furthermore, despite learning from the DEA that generic opioids seized in a 2009 Tennessee drug sting operation were traceable to one of its distributors, Sunrise Wholesale ("Sunrise"), Mallinckrodt, in the ensuing six weeks, blithely continued to send an additional 2.1 million tablets of oxycodone to Sunrise. In turn, Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who, in one day, prescribed 1,000 tablets to a single patient.[100] According to the internal government documents obtained by *The Washington Post*, Mallinckrodt's failure to report could have resulted in "nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[101]

371. During the DEA's investigation, Mallinckrodt sponsored the HDA (known as the Healthcare Distribution Management Association until 2016), an industry-funded organization that represents pharmaceutical distributors.[102] The HDA initiated the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (enacted April 19, 2016), which requires the DEA to give notice of violation and an opportunity to comply, to pharmacies and distributors, before

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https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.7ce8c975dd86.

99 *Id.*

100 *Id.*

101 *Id.*

102 *Sponsors: HDA's Annual Circle Sponsors*, HEALTHCARE DISTRIBUTION ALLIANCE, https://www.healthcaredistribution.org/hda-sponsors (last visited Mar. 4, 2019).

withdrawing licenses. This Act substantially weakened the DEA's ability to regulate manufacturers and wholesalers.[103]

372. In May 2014, Mallinckrodt posted a video entitled, "Red Flags". The video is a thinly veiled attempt to divert responsibility for the opioid epidemic away from manufacturers and wholesalers and toward individual pharmacists. The video was sponsored by the Anti-Diversion Industry Working Group, which is composed of Cardinal, Actavis, McKesson, Mallinckrodt, ABDC, and Qualitest (a part of Endo) – all of whom are also missing from the list of those responsible.[104]

373. In April 2017, Mallinckrodt reached an agreement with the DEA and the U.S. Attorneys for the Eastern District of Florida and Northern District of New York to pay $35 million to resolve a probe of its distribution of its opioid medications.[105] Mallinckrodt finalized the settlement on July 11, 2017, agreeing to pay $35 million while admitting no wrongdoing.[106]

9. Summary of Manufacturer Defendants' Unlawful Marketing Claims and Practices

Purdue	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life**

103 Chris McGreal, *Opioid Epidemic: Ex-DEA Official Says Congress is Protecting Drug Makers*, GUARDIAN (Oct. 31, 2016), https://www.theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma.

104 Anti-Diversion Industry Working Group, *et al.*, *Red Flags*, YOUTUBE (May 20, 2014), https://www.youtube.com/watch?v=WY9BDgcdxaM.

105 Linda A. Johnson, *Mallinckrodt to Pay $35M in Deal to End Feds' Opioid Probe*, U.S. NEWS & WORLD REPORT (Apr. 3, 2017, 6:47 PM), https://www.usnews.com/news/business/articles/2017-04-03/mallinckrodt-to-pay-35m-in-deal-to-end-feds-opioid-probe.

106 Press Release, U.S. Department of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017) (available at https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders).

a. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain vignettes," which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, "Paul," is described to be a "54-year old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively.

b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The *Policymaker's Guide* is still available online.

c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 Annual Report, and the guide currently is available online.

d. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

e. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book.

f. Purdue sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life. On information and belief, these deceptive representations were made to practitioners in the Randolph area.

Defendant misrepresents the risk of addiction

a. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading, "Indications of Possible Drug Abuse," shows pictures of the stigmata of injecting or snorting opioids – skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through

	oral use. Thus, these misrepresentations wrongly reassure doctors that as long as they do not observe those signs, they need not worry that their patients are abusing or addicted to opioids. In this same pamphlet, Purdue wrote that addiction "is not caused by drugs." Instead, Purdue assured doctors addiction happens when the wrong patients get drugs and abuse them: "it is triggered in a susceptible individual by exposure to drugs, most commonly through abuse." b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication is still available online. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction." c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. d. A Purdue-funded study with a Purdue co-author claimed that "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[107] The study relied only on the 1980 Porter-Jick letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. Although the term "low" is not defined, the overall presentation suggests the risk is so low as not to be a worry. e. Purdue contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and the claim is, in fact, untrue. Purdue was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion. f. APF's *Exit Wounds* (2009), sponsored by Purdue, counseled veterans that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests it is so low as not to be a worry.

107 C. Peter N. Watson, *et al.*, *Controlled-Release Oxycodone Relieves Neuropathic Pain: A Randomized Controlled Trial in Painful Diabetic Neuropathy*, 105 PAIN 71 (2003).

g. Purdue sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. On information and belief, these deceptive representations were made to practitioners in the Randolph area.

h. Purdue sales representatives told prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamperproof and, after a certain point, patients no longer experience a "buzz" from increased dosage. On information and belief, these deceptive representations were made to practitioners in the Randolph area.

i. Advertisements that Purdue sent to prescribers stated that OxyContin ER was less likely to be favored by addicts, and, therefore, less likely to be abused or diverted, or result in addiction. On information and belief, these deceptive representations were made to practitioners in the Randolph area.

j. In discussions with prescribers, Purdue sales representatives omitted discussion of addiction risks related to Purdue's drugs. On information and belief, these material omissions were made in presentations to practitioners in the Randolph area.

k. Another Purdue publication, the *Resource Guide for People with Pain* (2010), falsely assured patients and doctors that opioid medications are not addictive:

> ***Many people living with pain and even some healthcare providers believe that opioid medications are addictive. The truth is that when properly prescribed by a healthcare professional and taken as directed, these medications give relief – not a "high."***

Purdue falsely denied the risk of addiction, implied that addiction requires a "high," and promised that patients would not become addicted if they took opioids as prescribed.

l. *Opioid Prescribing: Clinical Tools and Risk Management Strategies* (2009) told doctors that "addiction is rare in patients who become physiologically dependent on opioids while using them for pain control," and that "behaviors that suggest abuse may only reflect a patient's attempt to feel normal."

Defendant deceptively claimed without scientific support that the risk of addiction could be avoided or managed

a. Purdue's unbranded website, *In the Face of Pain* (inthefaceofpain.com), states that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued

	prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds with" best medical practices.[108] b. Purdue sponsored a 2012 CME program titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes.* This presentation recommended that use of screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior. c. Purdue sponsored a 2011 webinar taught by KOL Dr. Lynn Webster, titled *Managing Patients' Opioid Use: Balancing the Need and Risk.* This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." d. Purdue sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction. On information and belief, these false representations were made to practitioners in the Randolph area. e. To "extend average treatment duration," Purdue deceptively claimed that patients' becoming dependent on its drugs was not dangerous or deadly, but "normal." Purdue taught doctors that: "Healthcare professionals should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction." Purdue deceptively claimed that physical dependence on its opioids was "a normal physiologic response" and "an expected occurrence," and no more dangerous than "many classes of medications" that are not addictive, including drugs used to treat high blood pressure. Purdue set as one of its "key messages" that "data support the use of opioids beyond 90 days and maintained through 52 weeks." **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such** a. Purdue published a prescriber and law enforcement education pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." b. Purdue distributed to physicians at least as of November 2006, and posted on its unbranded website, *Partners Against Pain*, a pamphlet copyrighted in 2005

[108] *See Fact Sheet: Protecting Access to Pain Treatment*, PURDUE PHARMA L.P., https://web.archive.org/web/20140423105047/http://www.inthefaceofpain.com:80/content/uploads/2011/12/factsheet_ProtectingAccess.pdf (last updated Apr. 2013).

and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct including "illicit drug use and deception," which it defined as indicative of pseudoaddiction or untreated pain. It also states:

> "Pseudoaddiction" is a term which has been used to describe patient behaviors that may occur when ***pain is undertreated***. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be ***distinguished from true addiction*** in that the behaviors resolve when the pain is effectively treated." (Emphasis added).

c. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. Purdue also spent over $100,000 to support distribution of the book.

d. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: "Pseudo-addiction describes patient behaviors that may occur when ***pain is undertreated***. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." (Emphasis added).

Defendant falsely stated or suggested that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation

a. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use.

b. Purdue sales representatives told prescribers that the effects of withdrawal from opioid use can be successfully managed. On information and belief, these false representations were made to practitioners in the Randolph area.

c. Purdue sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans's low potency and its extended release mechanism. On information and belief, these false representations were made to practitioners in the Randolph area.

Defendant suggested that high-dose opioid therapy was safe

a. Purdue's *In the Face of Pain* website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what – in their view – is a sufficient dose of opioids, they should find another doctor who will. In so

	doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands. b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones, which suggested that high-dose opioids are safe and appropriate and did not disclose the risks from high-dose opioids. This publication is still available online. c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language fails to disclose heightened risks at elevated doses. d. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit. e. Purdue sales representatives told prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses. On information and belief, these deceptive representations were made to practitioners in the Randolph area. **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. b. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. c. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013, and the 2013 version is still available for CME credit. The CME, *Overview of Management Options*, was edited by KOL Dr.

	Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses. d. Purdue sales representatives told prescribers that NSAIDs were more toxic than opioids. On information and belief, these false representations were made to practitioners in the Randolph area.
Cephalon	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Cephalon sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists. b. Cephalon sponsored the APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids when used properly "give [pain patients] a quality of life we deserve." The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the publication is currently available online. c. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. d. Cephalon sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life. On information and belief, these false representations were made to practitioners in the Randolph area. **Defendant misrepresented the risk of addiction** a. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which claims, among other things, that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme

	cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. c. In discussions with prescribers, Cephalon sales representatives omitted any discussion of addiction risks related to Cephalon's drugs. On information and belief, these deceptive representations were made to practitioners in the Randolph area. **Defendant deceptively claimed without scientific support that the risk of addiction could be avoided or managed** a. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed." **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such** a. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction. Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists. **Defendant suggested that high-dose opioid therapy was safe** a. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed. b. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations. c. Cephalon sales representatives assured prescribers that opioids were safe, even at high doses. On information and belief, these false representations were made to practitioners in the Randolph area. **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for

	severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. b. Cephalon sales representatives told prescribers that NSAIDs were more toxic than Cephalon's opioids. On information and belief, these false representations were made to practitioners in the Randolph area.
Collegium	**Defendant misrepresents the risk of addiction** a. In September 2016, the FDA's Office of Prescription Drug Promotion ("OPDP") sent advisory comments to Collegium regarding the company's presentations for Xtampza ER. In these advisory comments, OPDP recommended that Collegium revise its proposed presentations so that they did not misrepresent the approved indication or omit important context; misrepresent or omit important risk information; or omit other material information. In those comments, the OPDP also cautioned Collegium about failing to present risk information for Xtampza ER with a prominence and readability reasonably comparable to the presentation of benefits. On February 9, 2018, the FDA sent a warning letter to Collegium regarding Collegium's exhibit booth advertisement of Xtampza ER at the American Society Health-System Pharmacists (ASHP) Summer Meetings & Exhibition, which was held on June 3-7, 2017. The warning letter referenced its September 2016 advisory comments to Colleguim and voiced "concern[ ] that Collegium is promoting Xtampza ER in a manner that fails to adequately present the very serious risks of the drug, despite this direction from OPDP." The warning letter stated that Collegium's exhibit booth "failed to adequately provide material information about the drug's limitations of use and the serious and life-threatening consequences that may result from the use of the drug, thereby creating a misleading impression about the drug's safety." The warning letter further stated that "the exhibit booth presentation included a principal display panel that prominently presented benefit claims about the abuse-deterrent properties of Xtampza ER, but failed to include any information with respect to the drug's limitations of use, which state that due to the risks of addiction, abuse, misuse, overdose and death, Xtampza ER should only be used in patients for whom alternative treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Nor did the principal display panel include any information with respect to the indication or serious and life-threatening risks. . . ." b. Collegium Vice President Steven Passik, speaking at the Insight Exchange Network's 2018 conference "Responding to the Opioid Crisis: Litigation, Regulation & Reform," minimized risks of prescription opioids for the elderly, suggesting that the risk was minimal or nonexistent.

	Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs a. Collegium falsely stated in their presentation at the 2014 Jefferies Global Healthcare Conference that "prescription opioids remain the primary treatment for chronic pain[,]" although this was not (and is not) the case. Collegium repeated this false information in its March 2018 Form 10-K SEC filing. b. Defendant deceptively suggested that opioids with "abuse-deterrence technology" are safe. This is misleading and dangerous for several reasons: (1) many types of "abuse deterrent technology" are reversible, making the drug just as easily abused; (2) even where an opioid is less prone to abuse by adulteration, it remains prone to abuse in its pill form; (3) the primary danger of prescription opioids is addiction from overuse, which danger is not at all removed by changing a drug from immediate release to extended release; and (4) the focus on abuse intentionally confuses, even for the medical community, the issues of abuse and addiction, with many persons including those in the medical community misunderstanding that "abuse deterrent" somehow makes the use of the drug less addicting.
Janssen	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. On the cover, this guide features a man playing golf and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" (emphasis in the original). The myth/fact structure implies authoritative backing for the claim that does not exist. The targeting of older adults also ignored heightened opioid risks in this population. b. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with the APF, AAPM, and ASPMN, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying her experience would be representative. c. Janssen provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk.

Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder.

d. Janssen sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work. On information and belief, these false representations were made to practitioners in the Randolph area.

Defendant misrepresents the risk of addiction

a. Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and which its sales force distributed. This guide described a "myth" that opioids are addictive, and asserts as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." Although the term "rarely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use is not a problem.

b. Janssen contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Janssen was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion.

c. Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests the risk is so low as not to be a worry.

d. Janssen currently runs a website, *PrescribeResponsibly.com* (last modified July 2, 2015), which claims that concerns about opioid addiction are "overstated."

e. A June 2009 Nucynta Training module warns Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed."

f. Janssen sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. On

	information and belief, these deceptive representations were made to practitioners in the Randolph area. g. Janssen sales representatives told prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen's drugs. In truth, however, as set out in Nucynta's FDA-mandated label, Nucynta "contains tapentadol, an opioid agonist and Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit." On information and belief, these false representations were made to practitioners in the Randolph area. h. Janssen sales representatives told prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug. On information and belief, these false representations were made to practitioners in the Randolph area. i. In discussions with prescribers, Janssen sales representatives omitted discussion of addiction risks related to Janssen's drugs. On information and belief, these deceptive representations were made to practitioners in the Randolph area. **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such** a. Janssen's website, *Let's Talk Pain*, stated from 2009 through 2011 that "pseudoaddiction . . . refers to patient behaviors that may occur when ***pain is under-treated***" and "[p]seudoaddiction is ***different from true addiction*** because such behaviors can be resolved with effective pain management." (Emphasis added). **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation** a. A Janssen PowerPoint presentation used for training its sales representatives, titled "Selling Nucynta ER," indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days, or at high doses, and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term and at high doses will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use, when Janssen knew or should have known that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the

	likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew or should have known that the patients involved in the study were not on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain—the use for which Janssen promoted Nucynta ER. b. Janssen sales representatives told prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids. On information and belief, these false representations were made to practitioners in the Randolph area. **Defendant suggested that high-dose opioid therapy was safe** a. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased doses from opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."
Endo	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Endo sponsored a website, painknowledge.com, through APF and the National Initiative of Pain Control ("NIPC"), which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. b. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." c. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[109] d. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007). This book taught that relief of pain itself improved patients' function.

[109] FDA regulations require that warnings or limitations be given equal prominence in disclosure, and failure to do so constitutes "misbranding" of the product. 21 C.F.R. §202.1(e)(3); *see also* 21 U.S.C. §331(a).

	Responsible Opioid Prescribing explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." e. Endo provided grants to APF to distribute *Exit Wounds* to veterans, which taught that opioid medications "*increase* your level of functioning" (emphasis in the original). *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. e. Endo sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work. On information and belief, these false representations were made to practitioners in the Randolph area. **Defendant misrepresented the risk of addiction** a. Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence. b. Endo's advertisements for the 2012 reformulation of Opana ER claimed it was ***designed to be crush resistant***, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse" and Endo's "postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse. c. Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. d. Endo sponsored a website, PainAction.com, which stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." e. Endo sponsored CMEs published by APF and NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult* and *Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients[,]" which

	statement lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients. f. Endo distributed an education pamphlet with the Endo logo titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." g. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue. h. Endo contracted with AGS to produce a CME promoting the 2009 guidelines for the *Pharmacological Management of Persistent Pain in Older Persons*. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the AGS guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion. i. Endo sales representatives told Randolph prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. On information and belief, these false representations were made to practitioners in the Randolph area. j. Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the risk is so low as not to be a worry. k. In discussions with prescribers, Endo sales representatives omitted discussion of addiction risks related to Endo's drugs. On information and belief, these material omissions were made in representations to practitioners in the Randolph area. **Defendant deceptively claimed without scientific support that the risk of addiction could be avoided or managed** a. An Endo-supported publication, titled *Pain Management Dilemmas in Primary Care: Use of Opioids*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients

	with Pain, and advised that patients at high risk of addiction could safely (*e.g.*, without becoming addicted) receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such** a. Endo distributed copies of a book by KOL Dr. Lynn Webster entitled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that, when faced with signs of aberrant behavior, the doctor should regard it as pseudoaddiction and thus, increasing the dose ***in most cases . . . should be the clinician's first response.***" (Emphasis added). b. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction." **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation** a. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days. **Defendant suggested that high-dose opioid therapy was safe** a. Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," and once that occurs, further dose increases would not occur. Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it. b. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy, titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased . . . . You won't 'run out' of pain relief." **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Endo distributed a "case study" to prescribers, titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cites an example, meant to be representative, of a patient "with a massive upper gastrointestinal

	bleed believed to be related to his protracted use of NSAIDs" (over eight years), and recommends treating with opioids instead. b. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012, and closely tracked unique visitors to it. c. Endo provided grants to APF to distribute *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. d. Endo sales representatives told prescribers that NSAIDs were more toxic than opioids. On information and belief, these false representations were made to practitioners in the Randolph area.
Actavis	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "***most*** chronic benign pain patients do have ***markedly improved ability to function*** when maintained on chronic opioid therapy." (Emphasis added). b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function. c. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and "cause patients to enjoy their lives." The FDA warned Actavis such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[110]

110 Warning Letter, *supra* n.85.

	d. Actavis sales representatives told prescribers that prescribing Actavis's opioids would improve their patients' ability to function and improve their quality of life. On information and belief, these false representations were made to practitioners in the Randolph area. **Defendant misrepresented the risk of addiction** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction. c. Kadian sales representatives told prescribers that Kadian was "steady state" and had extended release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused. On information and belief, these false representations were made to practitioners in the Randolph area. d. Kadian sales representatives told prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused—and thereby less addictive—than other opioids. On information and belief, these deceptive representations were made to practitioners in the Randolph area. e. In discussions with prescribers, Kadian sales representatives omitted any discussion of addiction risks related to Actavis's drugs. On information and belief, these material omissions were made in presentations to practitioners in the Randolph area. **Defendant deceptively claimed without scientific support the risk of addiction could be avoided or managed** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction. **Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such** a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors like self-escalation of doses constituted "pseudoaddiction." **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation**

	a. Documents from a 2010 sales training indicate that Actavis trained its sales force that discontinuing opioid therapy can be handled "simply" and that it can be done at home. Actavis sales representative training claimed opioid withdrawal would take only a week, even in addicted patients. **Defendant suggested that high-dose opioid therapy was safe** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis's opioid, Kadian. **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs. b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, in older persons. c. Kadian sales representatives told prescribers that NSAIDs were more toxic than opioids. On information and belief, these false representations were made to practitioners in the Randolph area.
Mallinckrodt	**Defendant Mallinckrodt funded false publications and presentations.** a. In 2010, Mallinckrodt sponsored an initiative called "Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book is still available for sale and is available online at www.defeatchronicpainnow.com. b. Until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as "a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-

	based pain-management practices."[111] Among other content, the website included a handout titled "Oxycodone Safety Handout for Patients," which advised practitioners that: "Patients' fears of opioid addiction should be dispelled."[112] c. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb ("Gottlieb"), the current commissioner of the FDA, $22,500 for a speech in London, shortly after the U.S. presidential election.[113] Gottlieb has also received money from the Healthcare Distribution Alliance ("HDA"), an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.[114] **Defendant misrepresents the risk of addiction** a. "Defeat Chronic Pain Now!" advises laypeople who are considering taking opioid drugs that "[o]nly rarely does opioid medication cause true addiction."[115] b. "Oxycodone Safety Handout for Patients" included false and misleading statements concerning the risk of addiction associated with prescription opioids: Will you become dependent on or addicted to oxycodone? • After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.

111 *Pain Treatment Topics*, PAIN-TOPICS.ORG, https://web.archive.org/web/20070104235709/http://www.pain-topics.org:80/ (last updated Jan. 3, 2007).

112 Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, PAIN-TOPICS.ORG (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

113 Lee Fang, *Donald Trump's Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, INTERCEPT (Apr. 4, 2017, 2:15 PM), https://theintercept.com/2017/04/04/scott-gottlieb-opioid.

114 *Id.*

115 Galer, *et al.*, *supra* n.58.

- This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[116]

Defendant deceptively claimed without scientific support that the risk of addiction could be avoided or managed.

a. "Defeat Chronic Pain Now!" states that the issue of tolerance is "overblown," because "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance." In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that "[i]t is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

Defendant falsely stated or suggested the concept of "pseudoaddiction" and patients who only need more opioids, and should be treated as such.

a. The FAQ section of Pain-Topics.org contained the following false and misleading information downplaying the dangers of prescription opioid use:

> **Pseudoaddiction** – has been used to describe aberrant patient behaviors that may occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported by rigorous investigation, it has been widely observed that patients with unrelieved pain may become very focused on obtaining opioid medications, and may be erroneously perceived as "drug seeking." Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated. Along with this, two related phenomena have been described in the literature (Alford, et al. 2006):
>
> > **Therapeutic dependence** – sometimes patients exhibit what is considered drug-seeking because they fear the reemergence of pain and/or withdrawal symptoms from lack of adequate medication; their ongoing quest for more analgesics is in the hopes of insuring a tolerable level of comfort.
> >
> > **Pseudo-opioid-resistance** – other patients, with adequate pain control, may continue to report pain or exaggerate its presence, as if their opioid analgesics are

116 Kral, *et al.*, *supra* n.112.

	not working, to prevent reductions in their currently effective doses of medication. Patient anxieties about receiving inadequate pain control can be profound, resulting in demanding or aggressive behaviors that are misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief.[117] **Defendant's document "Commonsense Oxycodone Prescribing & Safety," falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: "Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[118]** **Defendant misbranded and marketed an unapproved drug** a. On March 30, 2009, Mallinckrodt received a letter from the FDA stating that Mallinckrodt was found to have been marketing an unapproved new drug, morphine sulfate concentrate oral solution 20 mg/ml, in violation of 21 U.S.C. §§331(d) and 355(a). Mallinckrodt had been marketing this unapproved formulation since 2005. The letter also stated that its unapproved morphine formulation was misbranded under 21 U.S.C. §352(f)(1) because the conditions it was intended to treat were not amenable to self-diagnosis and treatment. Adequate directions for such use, therefore, could not be written. As a result, introduction or delivery for introduction into interstate commerce of its unapproved morphine formulation violated 21 U.S.C. §§331(a) and (d).
Insys	Defendant sales representatives falsely told prescribers in the Randolph area that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation. Defendant sales representatives falsely told prescribers in the Randolph area that high-dose opioid therapy was safe, and advocated starting patients at a higher than approved dosage.

[117] *FAQs: Evidence-Based Answers*, PAIN-TOPICS.ORG, https://web.archive.org/web/20080821191924/http://www.paintopics.org/faqs/index1.php (last updated Jan. 8, 2008).

[118] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, PAIN-TOPICS.ORG (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf.

	Defendant sales representatives, in false representations to prescribers in the Randolph area, deceptively omitted the risks of opioids, including in comparison to NSAIDs Defendant created a system of insurance reimbursement to get its prescriptions approved that was based on fraud, such as advising the insurance companies that they were calling from the physician's office or falsely advising the insurance companies that the patient had cancer when (s)he did not.

D. Unlawful Conduct of Distributor Defendants

374. Under the statutory scheme set out in the CSA, enacted by Congress in 1970, wholesale pharmaceutical distributors were given the statutory obligation to have in place "effective controls" to prevent the "diversion" of controlled substances. 21 C.F.R. §1301.71(a). Once a pharmaceutical distributor detects a "suspicious order" of the controlled substance, it is obligated to take several mandatory steps. It must report the "suspicious order" to the DEA. Additionally, the wholesaler must investigate the suspicious order, document the result of the investigation, and, if not reasonably satisfied that the suspicious order is for the legitimate sale of the Retail End User, it must immediately halt the sale. *See Masters Pharm.*, 861 F.3d at 212-13. Plaintiff expressly denies that the reference to the CSA in this Complaint means that any claims "arise under" federal law within the meaning of 28 U.S.C. §1331.

375. Significantly, the Distributor Defendants' aforementioned statutory obligation to monitor and report suspicious orders does not arise solely under the federal CSA. Distributor Defendants have identical statutory obligations arising under Massachusetts state law. *See* Mass. Gen. Laws ch. 94C, §12(a)(2) (requiring that distributors of controlled substances must be registered and in "compliance with applicable federal, state, and local law"). More specifically, Massachusetts state law requires wholesale drug distributors of opioid pain medications to: "operate in compliance with applicable federal, state, and local laws and regulations" (247 CMR 7.04(9)(a)); register with the Massachusetts Board of Registration in Pharmacy, the Massachusetts

Department of Public Health, and DEA (247 CMR 7.04(9)(c)); and "keep records, maintain inventories, and make reports in conformance with the requirements of the Federal *Comprehensive Drug Prevention and Control Act of 1970* and the Federal Food, Drug and Cosmetic Act" (105 CMR 700.006(A)). As such, the Distributor Defendants have concurrent duties under both state and federal statutory law to monitor and halt suspicious orders of controlled substances. In addition, the Distributor Defendants have a common law duty that is owed to Plaintiff to operate their businesses (the distribution of opioids, which are controlled substances) in a lawful, reasonable, and safe manner. This common law duty includes taking reasonable measures to protect the public, and the governmental entity responsible for protecting the public health of its residents, from having the community become awash in an excessive amount of powerful and dangerous opioids.

376. A database known as the "Automation of Reports and Consolidated Orders System" ("ARCOS") was set up under the 1970 Controlled Substances Act. ARCOS is a comprehensive reporting system that shows the flow of every controlled substance from its point of manufacture, through the distributor, and on to the Retail End User.

377. The Commonwealth of Massachusetts has a similar reporting system for monitoring the flow of controlled substances, the Prescription Monitoring Program ("MAPMP"), which was established in 1992. Like the ARCOS database, the MAPMP has entered into "reciprocal agreements with other states that have compatible prescription drug monitoring programs to share prescription drug monitoring information among the states." Mass. Gen. Laws ch. 94C, §24A(a)(2).

378. All of the Manufacturer Defendants and Distributor Defendants have access to the MAPMP and ARCOS databases, and each is under concurrent obligations to enter into the databases all transactions with which it is involved for any controlled substance.

379. The ARCOS database is part of the architecture of a "closed system" assuring that every entity that touches a controlled substance is a DEA registrant. The Distributor Defendants have been tasked under state and federal statutory obligations to serve as primary gatekeepers or monitors to ensure that controlled substances are not allowed to flow into a community for illegitimate uses, referred to as "diversion."

380. The ARCOS system shows distribution of controlled substances to Retail End Users on the basis of their zip code. Therefore, one would be able to learn through these databases every time that a distributor made a sale to a Retail End User, within the zip code of the Town of Randolph, that appeared to be suspicious and which specific prescription opioid was shipped.

381. If the Distributor Defendants would permit access to such information, Plaintiff could document in this Complaint the gross number of suspicious sales made by each Distributor Defendant to the Town of Randolph in violation of its statutory obligation.

382. The Distributor Defendants will not permit such access, even in response to a FOIA request. Instead, they require the government to assert trade secret and confidentiality exemptions under Exemption 4 of FOIA.

383. The following chart[119] shows the only information publicly available from the ARCOS database, which reveals data from 2006 to 2017 on the basis of the first three digits of a zip code. Based on the first three digits of the relevant zip codes, the ARCOS database reveals the

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[119] *ARCOS Retail Drug Summary Reports*, U.S. D.O.J. https://www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html (last visited Mar. 4, 2019).

following grams (*i.e.*, thousands of milligrams) were delivered to the Greater Randolph area by chemical category of opioid.

ARCOS DATABASE – RANDOLPH, MA

Drug Name/Code	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Buprenorphine/9064	1,724.16	2,589.29	4,124.91	5,065.05	6,060.89	6,707.77	7,630.15	9,140.09	9,147.25	9,407.78	10,270.02	11,895.84
Fentanyl Base/9801	460.61	476.16	617.88	777.25	868.76	734.27	729.17	703.4	630.13	589	500.29	395.28
Hydrocodone/9193	11,891.11	14,864.55	17,591.92	20,039.70	19,369.58	19,621.95	18,613.11	17,577.79	20,705.54	13,112.96	10,699.79	8,667.85
Hydromorphone/9150	1,183.35	1,267.90	1,653.15	2,390.20	2,819.95	2,335.30	2,484.60	2,349.33	2,172.29	2,197.31	2,056.96	1,643.26
Morphine/9300	17,311.38	17,971.93	21,239.58	27,316.16	26,947.97	26,729.37	27,113.16	27,264.67	25,063.22	24,960.84	22,485.71	19,459.92
Oxycodone/9143	72,214.29	80,244.64	88,055.64	94,398.28	102,690.56	111,724.66	113,973.23	112,629.13	106,907.03	102,894.92	88,721.85	72,901.22
Oxymorphone/9652	9	89.48	119.57	306.88	396.77	556.68	465.91	428.8	321.51	421.23	331.41	296.01
Tapentadol/9780	---	---	---	427.5	1,795	2,923.50	4,173.50	4,254	4,024.50	3,710.50	3,507	3,479

384. Thus, for example, the amount of oxycodone sent to the Town of Randolph area in 2017 was 72,901.22 grams, ***or 72,901,220 mg***, the equivalent of 3,645,061pills of 20 mg each. Similarly, in 2012, its most recent peak distribution year, 113,973.23 grams, ***or 113,973,230mg***, the equivalent of 5,698,666pills of 20 mg each, of oxycodone was showered on the Randolph area.

385. Although the publicly available ARCOS information only stretches back to 2000, upon information and belief, additional recorded data exists for the period preceding 2000. If Distributor Defendants would permit access to this information, this longer timeline would show the dramatic increase in pharmaceutical opioid distribution in the Town of Randolph over the preceding ten years (*i.e.*, 1990-2000).

1. The "Big Three" Distributor Defendants

386. The "Big Three" Distributor Defendants, McKesson, Cardinal, and ABDC, control 85-90% of the market share in the United States for the distribution of prescription opioids.

387. It is reasonable to assume, and Plaintiff alleges on information and belief, that the Big Three Distributor Defendants have engaged, and continue to be engaged, in the unlawful

conduct of failing to report suspicious orders, reasonably investigate such orders, or halt such orders, thereby knowingly, recklessly, or negligently making grossly excessive distributions of opioid drugs into the Town of Randolph, and its surrounding areas, which threatened (and continues to threaten) the public health and safety of residents of the Town.

388. Each Big Three Distributor Defendant has repeatedly and purposely breached its duties under state statutory and common law with clear knowledge that a foreseeable result of its breach would be the diversion of dangerous prescription opioids for non-medical purposes.

389. On September 26, 2006, the DEA sent a letter to Distributor Defendants McKesson, Cardinal, and ABDC cautioning them not to "turn a blind eye to the suspicious circumstances." It further warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[120]

390. On December 27, 2007, the DEA sent another letter to Distributor Defendants McKesson, Cardinal, and ABDC warning them again of the importance of fulfilling their obligation and role as gatekeepers for the safe distribution of opioid prescriptions. The DEA letter stated, in part:

> Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.[121]

391. Each Distributor Defendant made the unlawful and unconscionable decision to continue suspicious sales, where it had strong reason to believe, or actually knew, that the

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120 Letter from Joseph T. Rannazzisi, Deputy Assist. Admin., Office of Diversion Control, to Cardinal Health (Sept. 27, 2006) (a copy of the letter is filed at *Cardinal Health, Inc. v. Holder*, No. 12-cv-00185 (D.D.C. Feb. 10, 2012), ECF No. 14-51).

121 Letter from Joseph T. Rannazzisi, Deputy Assist. Admin., Office of Diversion Control, to Cardinal Health (Dec. 27, 2007) (a copy of the letter is filed at *Cardinal Health, Inc. v. Holder*, No.12-cv-00185 (D.D.C. Feb. 10, 2012), ECF No. 14-8).

prescription drugs were being diverted and not being used for legitimate reasons, thereby subjecting Americans and Massachusetts residents, including residents of the Randolph community, to grievous harm up to, and including, death by overdose. Nevertheless, the Distributor Defendants, in derogation of their duty, and with foreseeable harm ensuing to the Plaintiff, continued to permit the sales to go through for one reason: the sales enhanced the Defendants' profits.

392. Upon information and belief, each Distributor Defendant knowingly made the business decision that payment of whatever fines were imposed was simply the cost of doing business, so long as their unlawful shipments and ensuing profits could continue.

393. Defendant McKesson agreed to pay a $150 million civil penalty to the DOJ on January 17, 2017 for violations of the CSA. While this settlement was premised on federal law violations, this same conduct would also constitute a violation of Massachusetts state law under Mass. Gen. Laws ch. 94C, §12(a), as well as 247 CMR 7.04(9)(a)-(b) and 105 CMR 700.006(A).

394. Additionally, in 2008, McKesson agreed to a $13.25 million civil penalty and entered into an administrative agreement for its failure to detect and report suspicious sales. The fine was the result of several district investigations by various DEA field divisions and U.S. Attorneys' offices, including the U.S. Attorney for the District of Massachusetts.

395. The DOJ announced through its Office of Public Affairs, in connection with the January 2017 fine to McKesson, that despite entering into the 2008 agreement, "[f]rom 2008 until 2013, McKesson supplied various U.S. pharmacies an increasing amount of oxycodone and hydrocodone pills, frequently misused products that are part of the current opioid epidemic."[122]

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122 *See* News Release, US DOJ Office of Public Affairs, *supra* n.6.

396. In December of 2016, Cardinal agreed to pay $44 million to the DOJ for its violations of the CSA ($34 million for itself and $10 million for a subsidiary). Again, this same conduct would be considered a violation of Mass. Gen. Laws ch. 94C, §12(a), as well as 247 CMR 7.04(9)(a)-(b) and 105 CMR 700.006(A).

397. On April 24, 2007, the DEA issued an order to show cause and an immediate suspension order against Defendant ABDC's Orlando, Florida, distribution center, alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, the DEA suspended ABDC's DEA registration at that facility. ABDC was allowed to continue shipments of controlled substances from its other facilities, so business was not interrupted.

2. The National Retail Pharmacies

398. Like the Big Three Distributor Defendants, the National Retail Pharmacies are participants in the opioid supply chain and registrants under both Massachusetts law and the CSA. As such, they are responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and investigating suspicious activities.

399. The National Retail Pharmacies' common law duties to the public run beyond those responsibilities they take on as distributors of opioids. Because the pharmacies that they own and operate are public-facing institutions with direct connections to the communities they serve, the National Retail Pharmacies as *dispensers* of opioids are uniquely situated to detect and prevent diversion at the local level.

400. Multiple factors observable to the National Retail Pharmacies may be "red flags" for diversion. For example, a pharmacy owned or operated by a National Retail Pharmacy is placed on notice for potential diversion when it receives an order that is unusually large in size, an order that is disproportionately large in comparison to the size of the community served, or an

order (or series of orders) that deviates from the ordinary pattern (or frequency) of orders in the community.

401. Other "red flags" observable to pharmacies include (1) prescriptions written by doctors who write significantly more prescriptions (or prescriptions for higher dosages or durations) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for certain periods in legitimate use, but are being refilled at shorter intervals; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that "look too good" or upon which the prescriber's handwriting is too legible; (5) prescriptions with quantities or dosages that differ from typical medical usage; (6) prescriptions that use notations not complying with standard abbreviations and/or that contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing variant handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

402. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

403. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

404. Despite their obligations, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly. Upon information and belief, the National Retail Pharmacies have allowed diversion to occur in Randolph and the surrounding communities. They have also allowed diversion to occur at locations much further afield, knowing that sophisticated

illicit drug networks would transfer the diverted opioids to Randolph and the surrounding communities.

405. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. Under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

406. Upon information and belief, this problem was compounded by the National Retail Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

407. Upon information and belief, the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

408. Upon information and belief, the National Retail Pharmacies failed to analyze (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

409. Upon information and belief, the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

410. Upon information and belief, the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

411. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

412. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

413. Defendant CVS is a repeat offender and recidivist: the company has paid fines totaling millions of dollars as the result of a series of investigations by the DEA and the United States Department of Justice. It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA. Upon information and belief, there are, and/or at times relevant to this Complaint have been, over 410 CVS pharmacies in Massachusetts.

414. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores in Massachusetts and New Hampshire violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014. Among other things, the DOJ had alleged the CVS stores ignored red flags suggesting that prescriptions were forged, that patients were engaged in "doctor shopping," and that the forged prescriptions had been written for quantities of oxycodone that were excessive under the circumstances. The government also alleged that CVS failed to confirm the identities of prescribers even though relevant information was available through the DEA's website. The DEA estimated that the street value of the diverted pills in these cases was over $1 million.

415. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

416. Walgreens is the second largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in

fiscal 2017. Upon information and belief, there are, and/or at times relevant to this Complaint have been, 270 Walgreens pharmacies in Massachusetts.

417. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.

418. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on the number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

419. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

420. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and did not use sound professional judgment when dispensing opioids and other controlled substances—despite the

context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

421. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid-branded stores represent the largest drugstore chain on the East Coast and the third largest in the United States. Upon information and belief, there are, and/or at times relevant to this Complaint have been, 85 Rite Aid-branded pharmacies in Massachusetts.

422. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that led to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated.

423. In January 2019, Rite Aid agreed to a $177,000 settlement with the Massachusetts Attorney General in connection with accepting cash payments for controlled substances, including opioids, in violation of Medicaid regulations.

424. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

425. On information and belief, because of (among other sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug

sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

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426. The repeated shipments and dispensations of suspicious orders, year-after-year, by each Distributor Defendant demonstrated its reckless conduct and criminal indifference to its statutory and common law obligations, which it knew would result in a great probability of causing substantial harm to a great many American communities, including Randolph.

427. The Distributor Defendants' failure to detect, report, investigate, and halt suspicious orders is a direct, foreseeable, and proximate cause of the excessive amounts of opioids that have inundated the Town of Randolph in numbers far beyond any legitimate medical need.

428. Plaintiff seeks damages from the Distributor Defendants as reimbursement for the costs it incurred, is still incurring, and will, for the foreseeable future, continue to incur to try to contain and mitigate the hazards to public health and safety caused by the Distributor Defendants. Additionally, Plaintiff seeks injunctive relief, including payment for future costs required to eliminate the public nuisance caused by the Distributor Defendants' unlawful and unconscionable acts.

E. Defendants Are Estopped from Asserting Statute of Limitations or Laches Defenses

1. The Manufacturer Defendants Fraudulently Concealed Their Misconduct

429. The Manufacturer Defendants, both individually and collectively, made, promoted, and handsomely profited from their misrepresentations and material omissions about the risks and benefits of opioids for chronic pain, even though they knew that their misrepresentations and material omissions were false and deceptive. The long-held medical view, along with research and clinical experience prior to the commencement of the Manufacturer Defendants' campaign of

disinformation, established that opioids are highly addictive and responsible for a long list of very serious adverse outcomes. Upon information and belief, the FDA warned Defendants of the questionable basis of chronic long-term use of opioids, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the devastating harm from long-term opioid use. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations.

430. Endo and Purdue have recently entered agreements in New York State prohibiting them from making some of the same misrepresentations described in this Complaint. Collegium has been issued an FDA Warning Letter, as recently as February 2018, for engaging in the identical egregious misrepresentations that have caused the opioid addiction and overdose epidemic. More specifically, the Warning Letter asserts that Collegium has materially omitted the description of risks of addiction, abuse, overdose, and death from its oxycodone product and has failed to disclose that the product is only medically indicated for use if safer alternative treatments have been tried by the patient without success.

431. At all times relevant to this Complaint, the Manufacturer Defendants took steps that were designed to, and did, in fact, fraudulently conceal their deceptive marketing and unlawful conduct. For example, the Manufacturer Defendants disguised their role in the deceptive marketing of long-term opioid therapy by secretly funding and working through third parties, like Front Groups and KOLs. The Manufacturer Defendants never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. They did not reveal that CMEs on pain management had been infiltrated by persons that were

being paid to espouse the deceptive position of the Manufacturer Defendants that opioids were a safe modality for the treatment of chronic pain and to suppress the presentation of any other views.

432. The Manufacturer Defendants ran websites with generic names, such as painknowledge.com, that were actually funded, in substantial part, by the Manufacturer Defendants.

433. The Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. For example, the Manufacturer Defendants, other than Insys and Collegium, distorted the import of the Porter/Jick Letter to the NEJM (*see supra* at ¶¶198-202). The Manufacturer Defendants, other than Insys and Collegium, invented "pseudoaddiction" and promoted it to an unsuspecting medical community (*see supra* at ¶¶178-186). The Manufacturer Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants spent tens of millions of dollars over a period of years on a misinformation campaign and so permeated the avenues where information was disseminated to physicians and the medical community that it was difficult, if not impossible, for medical professionals to detect the truth.

434. The Manufacturer Defendants also promoted the false information regarding the relative safety of chronic opioid use directly to the public, especially directing their messages to the elderly and veterans (*see supra* at ¶¶296-314). The deception was so widespread that it was difficult for the public to learn the true risk of opioids.

435. Similarly, it was difficult, if not impossible, for Plaintiff to detect the harm being perpetrated on its community and citizens by the explosive use of opioids for everyday pain. Plaintiff did not, and could not, have known of the existence or scope of the Manufacturer

Defendants' industry-wide fraud and could not have acquired such knowledge through the exercise of reasonable diligence.

2. Distributor Defendants Concealed Their Violations of State Statutory and Common Law as Well as Federal Law

436. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the Commonwealth of Massachusetts, Randolph, and the Town's medical community, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws.

437. The Distributor Defendants concealed their unlawful conduct and fraudulently assured the public, the Commonwealth of Massachusetts, and the Town of Randolph that they were fully compliant with their obligations. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[123]

438. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[124]

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[123] Lenny Bernstein, *et al.*, *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: 'No One Was Doing Their Job'*, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.30f8a1ea7541.

[124] Scott Higham, *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, WASH. POST (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

439. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through their trade associates, Healthcare Distribution Management Association ("HDMA") and National Association of Chain Drug Stores ("NACDS"), filed an *amicus* brief, which stated:

> Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.

Masters Pharm,, Inc. v. U.S. Drug Enf't Admin., No. 15-1335, 2016 WL 1321983, at *25 (D.C. Cir. Apr. 4, 2016). Thus, while acknowledging their duty to report suspicious sales, the Distributor Defendants falsely represented that they acted in compliance with those obligations.

440. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS and MAPMP databases, that will confirm the extent of their wrongful and illegal activities. For example, they refused to allow the DEA to reveal the amount of prescription opioids distributed to the Randolph area by name of distributor and product trade name, claiming trade secret, confidentiality, or privilege, in response to FOIA requests.

3. The Statute of Limitations and Laches Doctrine Do Not Apply Here

441. The medical community, patients, their families, the Commonwealth of Massachusetts, and Plaintiff were duped by the Manufacturer Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the Commonwealth of Massachusetts and Town of Randolph.

442. The medical community, patients, their families, the Commonwealth of Massachusetts, and Plaintiff were duped by the Distributor Defendants' campaign to misrepresent and conceal the truth that they were dumping opioids into the Town of Randolph, despite being alerted to the fact that year-after-year they were ignoring their obligation under state and federal law to protect the community from suspicious sales.

443. All Defendants intended that their actions and omissions would be relied upon, including by Plaintiff. Plaintiff did not know, and did not have the means to know, the truth due to Defendants' actions and omissions.

444. Plaintiff reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

445. The purposes of the statute of limitations period and laches doctrine are satisfied in this case because Defendants cannot claim prejudice where Plaintiff filed suit promptly upon discovering the facts essential to its claims, described herein, which Defendants knowingly concealed. Plaintiff did not, and could not, have known through the exercise of reasonable diligence of its causes of action as a result of Defendants' conduct.

446. Defendants' torts based upon misrepresentation and deceit continues to this day. They continue their deception to avoid compliance with their legal obligations by falsely characterizing the opioid epidemic in Plaintiff's community, as well as the nation, as one of "abuse." In truth, as the Defendants have known for years, the proximate cause of the epidemic is the "use" of opioids – which have been described as "heroin pills" – for chronic pain, which use was always highly dangerous, medically contraindicated, and likely to cause addiction in the widespread manner exactly as it has occurred.

447. Plaintiff continues to suffer harm from the public nuisance created by the unlawful actions by the Defendants and, until the nuisance is abated, the harm to the Plaintiff will continue for the foreseeable future.

F. Damages to the Town of Randolph

448. As a foreseeable, direct, and proximate result of the unlawful conduct of the Defendants, along with those of the third-party Front Groups and KOLs, who were assisted and controlled by the Manufacturer Defendants, the Town of Randolph, along with many other

communities in the United States, has been subjected to devastating public health epidemics of addiction and overdose.

449. As discussed *supra* at ¶¶123-30, it is well-recognized and well-established biology that, once a person becomes addicted to opioid stimulation of opioid receptors in his or her brain, that person is compelled to continue to crave and seek out that stimulation, even if the original prescription drug, which began the addiction, is no longer available, either because it is too expensive or the prescription opioids have become more restricted. Absent treatment, which is often not effective, the opioid-addicted person will use illicit opioids, such as heroin, or fentanyl, or a combination of those opioids, if they are available. People who are addicted to prescription opioid painkillers are 40 times more likely to become addicted to heroin.[125] As of 2013, four out of five new street-level heroin users nationally (*i.e.*, 80%) began their addiction through the use of prescription pain medications.[126]

Nuisance Abatement Expenditures

450. Plaintiff has been forced to spend extraordinary funds each year in its effort to combat the public nuisance created by Defendants. Plaintiff has incurred, and continues to incur, costs resulting from the treatment of persons affected by opioid addiction, from the management and amelioration of the opioid epidemic, and from the allocation of social services and Town programs to different aspects of the crisis. These costs include, without limitation, costs borne by Randolph resulting from increased 911 calls, hospitalizations and longer stays in the hospital for

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125 *See* CTRS. FOR DISEASE CONTROL AND PREVENTION, TODAY'S HEROIN EPIDEMIC (July 7, 2015), https://www.cdc.gov/vitalsigns/heroin/index.html.

126 Pradip K. Muhuri, *et al.*, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ DATA REVIEW (August 2013), https://archive.samhsa.gov/data/2k13/DataReview/DR006/nonmedical-pain-reliever-use-2013.pdf.

treatment of opioid addiction; costs borne by Randolph resulting from unrelated illnesses that involve more complex treatment due to the combination of the illness plus opioid addiction; costs borne by Randolph relating to 911 calls, hospitalizations and longer stays for neo- natal care for addicted newborns or maternal care for addicted mothers; Randolph's cost of managing escalated overdose rates; and the cost to Randolph of implementing prevention and education efforts in the community, among others.

451. The issue of trying to "get ahead of the epidemic" or at least staunch its devastation is a priority issue for Randolph. The Town, its departments, and employees, in partnership with community groups and other Towns, are working tirelessly in an effort to curb the epidemic and its destructive wake.

452. Many of the services that Randolph is now forced to provide, oversee, and/or coordinate are not traditionally considered to be municipal health services, but have become necessary for the Town to undertake to try to protect its residents' lives and health and the well-being of its community from the devastating effects of the opioid epidemic created and fueled by Defendants.

453. Among the expenditures incurred and the services rendered, which will continue to be needed and expanded for the foreseeable future, by Randolph to try to abate the public nuisance are the following:

(a) losses caused by the decrease in funding available for Plaintiff's public services due to diversion of said funds to other public services designed to address the opioid epidemic;

(b) costs for providing healthcare and additional therapeutic, prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses treatment and prevention;

(c) costs associated with providing emergency healthcare, including without limitation, response to and provision of first aid, investigative inquiries into opioid related overdoses, resulting in emergency medical service intervention and at times, death;

(d) costs of training and re-training emergency and/or first responders in the proper treatment of opioid overdoses and addiction;

(e) costs associated with providing emergency and/or first responders with opioid antagonists, such as naloxone, used to block opioid overdoses;

(f) costs associated with continually re-supplying public officials with opioid antagonists, since multiple doses are often necessary to revive a person who is experiencing an opioid overdose;

(g) costs associated with the increased need for overtime hours worked by Town employees, including without limitation, overtime pay for emergency workers responding to the opioid crisis;

(h) costs for providing mental-health services, treatment, rehabilitation services, and social services to victims of the opioid epidemic and their families;

(i) costs for providing treatment of infants born with opioid-related medical conditions or born dependent on opioids due to drug use by a mother during pregnancy;

(j) costs associated with law enforcement and public safety relating to the opioid epidemic, including, but not limited to, attempts to stop the flow of opioids into local communities, prevent the current opioid epidemic from spreading and worsening,

deal with crime that has directly resulted from the increased drug-addicted population, and respond to and take reports, investigate, arrest and prosecute street-level dealers and opioid-addicted individuals in regards to property crimes and crimes against persons – driven by their addictions to secure funds to purchase opioids;

(k) costs associated with services provided by Randolph Public Schools for school children traumatized by addiction issues or separated from their homes as the result of addiction issues;

(l) loss of tax revenue due to the decreased efficiency and size of the working population in Plaintiff's community;

(m) costs associated with clean-up of public parks, spaces, and facilities of needles and other debris and detritus of opioid addiction;

(n) losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root;

(o) losses caused by diminished property values in the form of decreased business investment and tax revenue in neighborhoods where the opioid epidemic has taken root.

454. The above list is only illustrative and does not include every category of expense, investment, and necessary service that has been, and will continue to be, incurred by Randolph as a direct and proximate result of Defendants' wrongdoing.

Overdose-related Deaths

1. Commonwealth of Massachusetts

455. As a foreseeable result of increases in opioid drug prescriptions in a community, there follows increases in overdoses, deaths, and addictions.

456. Massachusetts has been experiencing a heroin overdose outbreak. For example, 2014 was the first year since 1999 that the overdose rate in Massachusetts was more than double the national average.[127] In 2014, then-Governor Deval Patrick declared a public health emergency in Massachusetts in response to the growing opioid addiction epidemic, creating several programs and initiatives, which, according to Cheryl Bartlett, the Commissioner of the Massachusetts Department of Public Health, in 2014, were meant to "slow the rise of this dangerous addiction . . . raise awareness in our communities, help save loved ones who tragically fall down from their disease and build important bridges to long-term recovery."[128]

457. Scientific studies support the finding that increases in opioid overdoses in general (as well as fatal opioid overdoses) in a community follow by several years the peak number of prescription opioids in a community.

458. The Commonwealth of Massachusetts saw 379 opioid-related deaths in 2000.[129] In 2012, that number had nearly doubled with 742 opioid-related deaths.[130] By 2016, opioid-related deaths had skyrocketed to 2,096 deaths,[131] which constituted a 182% increase from 2012 and a staggering 453% increase from 2000. The following chart from the Massachusetts Department of Public Health tracks this rise in opioid-related deaths:

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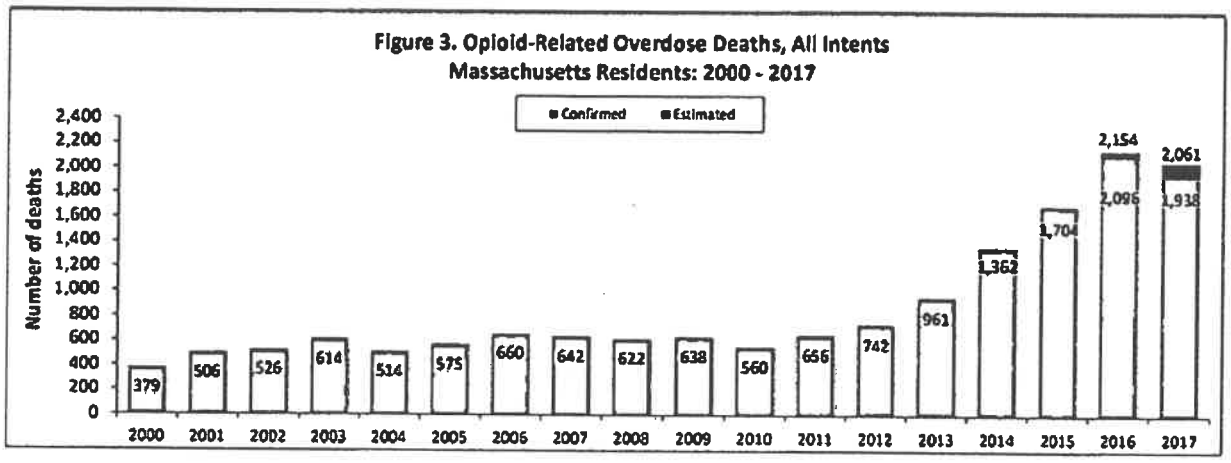
127 *See Massachusetts Opioid Epidemic*, *supra* n.21.

128 Matt Perkins, *Gov. Patrick Declares Opiate Addiction a Public Health Emergency*, STOUGHTON PATCH (Mar. 28, 2014), https://patch.com/massachusetts/stoughton/gov-patrick-declares-opiate-addiction-a-public-health-emergency

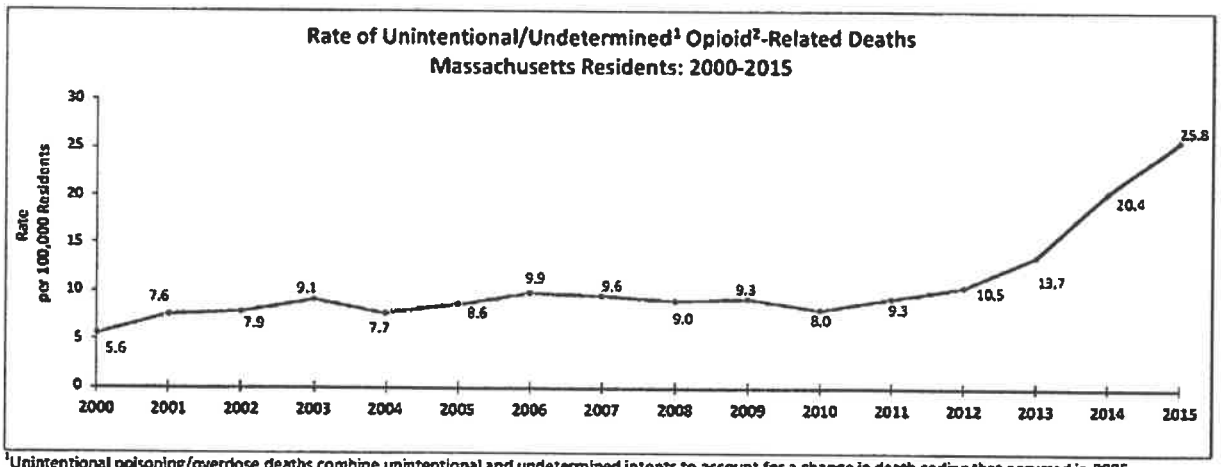
129 MASS. DEPT. PUB. HEALTH, DATA BRIEF: OPIOID-RELATED OVERDOSE DEATHS AMONG MASSACHUSETTS RESIDENTS (2018), https://www.mass.gov/files/documents/2018/11/16/Opioid-related-Overdose-Deaths-among-MA-Residents-November-2018.pdf.

130 *Id.*

131 *Id.*



459. In 2015, the estimated rate of unintentional opioid-related overdose deaths was 25.8 deaths per 100,000 residents. This represents a 26% increase from the rate of 20.4 deaths per 100,000 residents in 2014.



[1] Unintentional poisoning/overdose deaths combine unintentional and undetermined intents to account for a change in death coding that occurred in 2005. Suicides are excluded from this analysis.
[2] Opioids include heroin, opioid-based prescription painkillers, and other unspecified opioids. This report tracks opioid-related overdoses due to difficulties in identifying heroin and prescription opioids separately.

460. Concurrently, nonfatal opioid overdoses have seen a similar rise. Between 2011 and 2015, nonfatal overdoses increased by 200%, with the total number of such overdoses exceeding 65,000.[132]

132 *An Assessment of Fatal and Nonfatal Opioid Overdoses in Massachusetts*, *supra* n.22.

2. Town of Randolph

461. Like the Commonwealth of Massachusetts, the Town of Randolph has been struck particularly hard by the influx of opioid drugs and resulting boom in the number of opioid addicts. For example, the Massachusetts Department of Public Health has reported that the number of opioid-related deaths in Randolph has risen from 5 deaths in 2013 to 12 in 2015.[133] In short, the Town has seen the number of opioid-related overdose deaths more than double from 2013 to 2015.

Increased Hospitalizations and Related Health Care Costs

462. Despite the Randolph area's community of physicians, nurses, and clinicians who tireless work to save lives, the opioid epidemic continues to outpace their efforts.

463. Opioid-related injury and illness in Massachusetts, in general, and Randolph, in particular, extends well beyond overdoses. Massachusetts had by far the highest rate of opioid-related emergency room visits in 2014, at 450.2 per 100,000 population, according to the latest available data from the Maryland-based Healthcare Cost and Utilization Project ("HCUP"), which included information from 30 states.[134] The national average was 177.7.[135] Massachusetts had the second highest rate of opioid-related hospitalizations in 2014, with 393.7 opioid-related inpatient hospital stays per 100,000 population, according to the same report from HCUP.[136] The national average was 224.6.[137]

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133 *Number of Opioid-Related Overdose Deaths*, *supra* n.18.

134 Andrew J. Weiss, *et al.*, OPIOID-RELATED INPATIENT STAYS AND EMERGENCY DEPARTMENT VISITS BY STATE, 2009-2014, Healthcare Cost and Utilization Project (Dec. 2016 and revised Jan. 2017), https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.jsp

135 *Id.*

136 *Id.*

137 *Id.*

464. According to the CDC, an increase in Hepatitis C in the United States is directly tied to intravenous injection of opioids. Once again, Massachusetts is no exception to this trend. For example, on September 24, 2018, the Massachusetts Department of Public Health issued a public alert to local health officials, including those in Randolph, about an outbreak of Hepatitis A among the homeless and individuals suffering from drug addiction. Approximately 65 cases of the virus were diagnosed, resulting in at least one death. In addition, the reported rates of acute Hepatitis C in Massachusetts increased by 1133% from 2011 to 2015,[138] an increase that resulted largely from intravenous use of drugs, including OxyContin and other prescription painkillers, stemming from the opioid epidemic.

465. In short, opioid addiction creates its own health issues for individuals, as well as exacerbating or making it more difficult to treat other non-opioid-related illnesses and injuries. Increased hospitalizations from opioid overdoses put undue strain on the Town's already taxed hospital system and emergency medical system. Defendants' deceptive conduct has resulted in forcing the Town to shoulder the burden of these increased costs.

466. Furthermore, individuals seeking addiction treatment in Massachusetts are primarily seeking treatment for opioid-related addiction. In particular, as of 2015, approximately 58% came for treatment because of opioids compared to alcohol (38%), marijuana (4%) and all other drugs (5%).[139] As the following chart[140] indicates, from 2000-2015 opioid has become the primary substance of use of all individuals seeking addiction treatment in Massachusetts:

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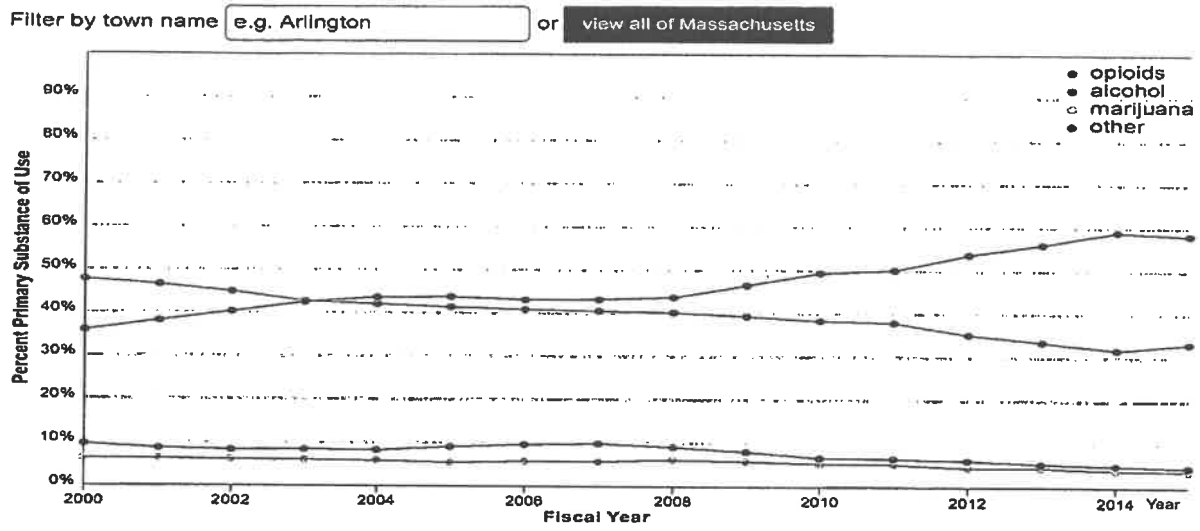
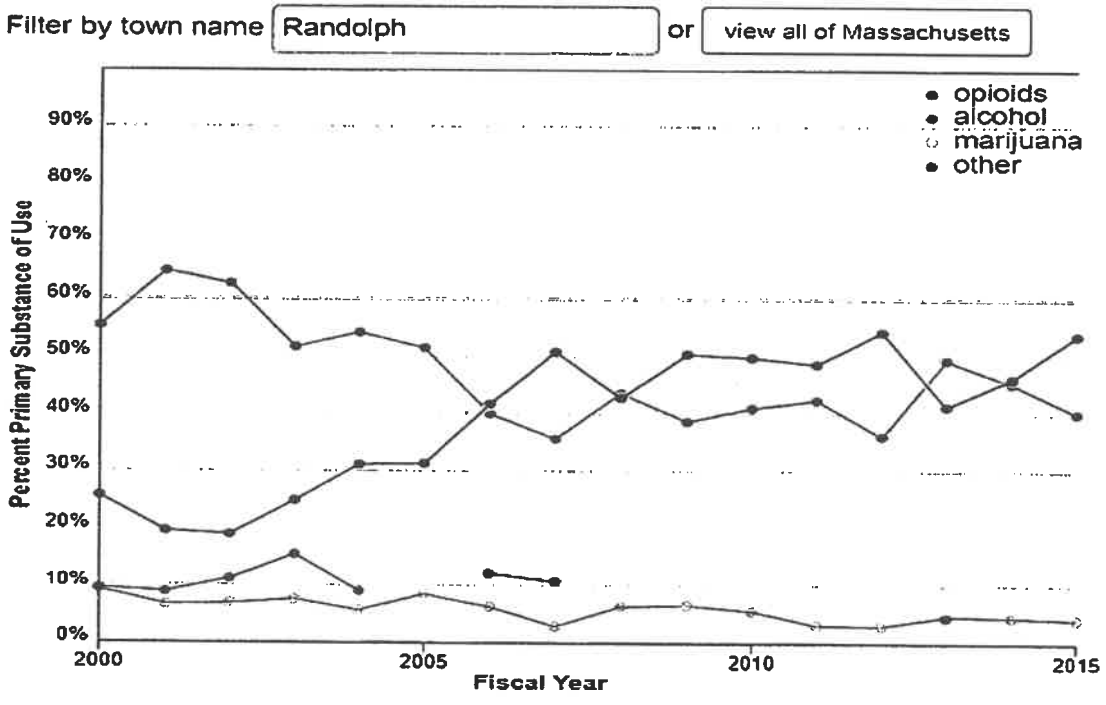
138 CTRS. FOR DISEASE CONTROL & PREVENTION, MASSACHUSETTS – STATE HEALTH PROFILE (Version 1.8 2015), https://www.cdc.gov/nchhstp/stateprofiles/pdf/massachusetts_profile.pdf.

139 *The Massachusetts Opioid Epidemic: A Data Visualization of Findings from the Chapter 55 Report*, MASS. DEP'T OF PUB. HEALTH, www.mass.gov/chapter55 (last visited Mar. 4, 2019).

140 *Id.*



467. . The percentage of individuals seeking treatment for opioid addiction has followed a similar trend in Randolph. In particular, as the following chart indicates, at the time of admission, 54% of individuals surveyed identified opioids as the primary substance of use for which they were seeking treating:



Neo-Natal Care Costs

468. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS"). These infants usually experience painful withdrawal from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms.

469. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening.

470. Opioid exposed newborns present challenges for doctors, nurses, and hospitals because detoxification can be a complex process requiring weeks of inpatient care.[141]

471. A March 17, 2017 report, issued by the Commonwealth of Massachusetts's Interagency Task Force, on newborns with NAS states that the rate of reported prenatal opiate exposure in Massachusetts rose from 2.6 per 1,000 hospital births in 2004 to 14.7 in 2013 – an increase of more than 500%. The rise in NAS has been referred to as an "epidemic within an epidemic." As the following chart indicates,[142] the opiate addiction epidemic in Massachusetts has resulted in a more than six-fold increase in the number and rate of infants born with opiate dependence between 2004 and 2013:

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141 Urbano L. França, *et al.*, *The Growing Burden of Neonatal Opiate Exposure on Children and Family Services in Massachusetts*, 21 CHILD MALTREATMENT 80 (2015), *available at* https://www.researchgate.net/publication/283754520_The_Growing_Burden_of_Neonatal_Opiate_Exposure_on_Children_and_Family_Services_in_Massachusetts.

142 *Id.*

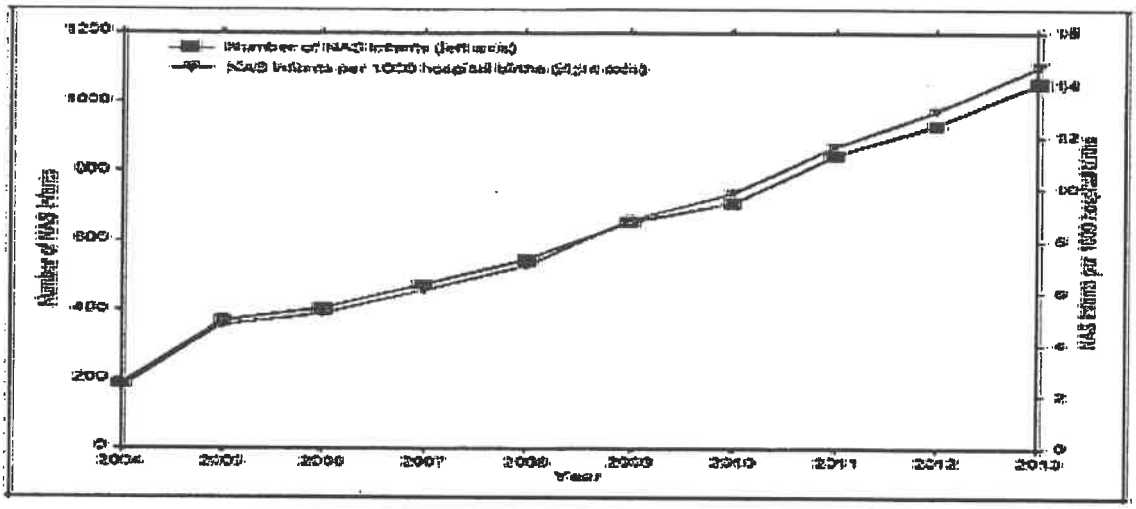


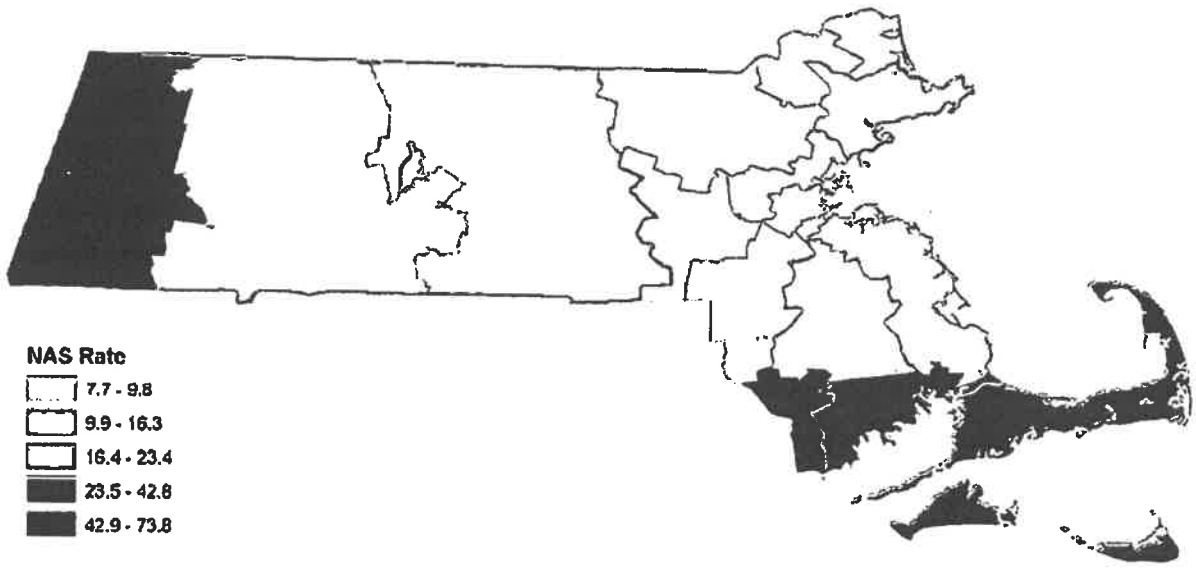
Figure 2. Evolution of the number and rate of neonatal abstinence syndrome in Massachusetts from 2004 to 2013.

472. Researchers strongly suspect the actual figures are higher; more than 1,300 Massachusetts babies, or about 17.5 per 1,000 hospital births, were found to have both heroin and/or other opioids in their system in 2013 alone.

473. As the following map[143] indicates, the rate of NAS discharges in the area around Randolph in 2015 stands with the Massachusetts average, ranging from 9.9 to 23.4per 1,000 hospital births:

143 MASS. HEALTH POLICY COMM'N, HEALTH POLICY COMMISSION INVESTMENTS IN NAS (Mar. 13, 2017), https://malegislature.gov/Reports/4709/SD2134%20--%20NAS%20Health%20Policy%20Commission%20Investments.pdf.

Rate of NAS discharges per 1,000 live births, by HPC region, in 2015



474. The average length of stay in Massachusetts for an infant requiring treatment for NAS is 19 days, with an average total cost of $30,000 as of 2013.[144]

Direct Purchases of Opioids and Related Costs

475. Prescription drug spending has historically been a "major driver" of health care costs in Massachusetts.[145] Plaintiff has been directly damaged through its payments of its share of health care costs for opioid therapy (and the frequent ensuing payments for addiction-related treatment) that was unwarranted and potentially dangerous for its employees, retirees, and their

144 COMMONWEALTH OF MASS., STATE PLAN FOR THE COORDINATION OF CARE AND SERVICES FOR NEWBORNS WITH NEONATAL ABSTINENCE SYNDROME AND SUBSTANCE-EXPOSED NEWBORNS (2017).

145 Shira Schoenberg, *Hospital Readmissions, Drug Costs, Telemedicine All Addressed in Massachusetts Senate Health Care Costs Bill*, MASSLIVE (Oct. 17, 2017), https://www.masslive.com/politics/index.ssf/2017/10/hospital_readmissions_drug_cos.html.

families by providing a medical insurance plan and workers' compensation program for its employees.

476. The filling of opioid prescriptions pursuant to Randolph employees' health insurance plan coverage is a significant element in the calculation of the health care costs paid by the Town.

477. The fact that the Town of Randolph would incur increased expenses as the result of the use of such ineligible and unnecessary prescriptions on behalf of its employees, retirees, and their families was the foreseeable and intended consequence of Manufacturer and Individual Defendants' fraudulent marketing scheme.

478. The Town of Randolph has also shouldered significant health-related costs outside of its health insurance program as a result of Defendants' actions. For instance, when Randolph employees are prescribed opioids for chronic pain they may be forced to miss work because the drugs' effects interfere with their ability to work.

479. In fact, recent studies suggest that opioids actually slow recovery times, keeping employees out of work longer than they would have been had they not taken these unnecessary pharmaceuticals. If those employees become addicted to the opioids, they are likely to miss even more work. Because of Defendants' misstatements, Randolph's employees have had losses in work time, which result in substantial losses to the Town.

480. And as set forth above, the costs incurred by the Town relating to filling the opioid prescriptions is just a small part of the total cost to Randolph for prescriptions of opioids. Under its workers' compensation plan, the Town pays for portions of doctors' visits, lab work, and other costs related to the prescription of opioid painkillers. Had Defendants told the truth about the risks

and benefits of opioids, the Town would not have had to pay for these drugs or the costs related to their prescriptions.

481. As both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme, health care providers prescribed and Randolph paid for a variety of costs and fees dictated, in part, by the cost of using opioids to treat chronic pain. Indeed, Defendants entire purpose of convincing the medical and general community to support chronic opioid therapy was to get doctors to prescribe and payors, such as the Town of Randolph, to pay for long-term prescriptions of opioids to treat chronic pain, despite the absence of genuine evidence supporting chronic opioid therapy and the existence of evidence to the contrary.

482. Health plans and workers' compensation programs generally require that medical treatments be medically necessary or reasonably required. Defendants' misrepresentations were designed to induce payments for opioids in circumstances where these criteria were not met, resulting in significant unjustified costs to the Town health plans and workers' compensation program. But for Defendants' fraudulent and deceptive marketing, prescribers would have accurately understood the risks and benefits of opioids and would not have prescribed opioids where not medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but the core of prescribers' decision-making.

Expenses Related to Opioid Education and Training

483. The Town of Randolph has been forced to expend massive amounts of time, money, and resources on re-educating and training its public safety employees on the appropriate way to proscribe opioid pain medications.

484. Members of the Randolph Police and Fire Departments receive training in the administration of naloxone in order to curb the growing number of overdose deaths occurring within the Town.

485. Randolph Town and school nurses are increasingly being exposed to individuals suffering from opioid-related medical conditions,

486. Concurrently, the Town, including Randolph Public Schools, has also borne expenses attributable to the opioid epidemic. The Town provides wellness programs on opioid addiction and prevention.

487. The Town also needs to provide coverage when employees are absent due to their own addiction issues or due to caring for addicted family members, attending funerals for victims of opioid overdoses, etc.

Emergency Treatment Costs

488. The opioid crisis created by Defendants has also resulted in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone, the antidote to opioid overdose.

489. Massachusetts consistently ranks as having the highest rates of opioid-related inpatient stays across all patient locations and income groups in the United States.[146] The Town experienced an increase in the rate of opioid-related hospitalizations as well.

490. Typically, Randolph Fire Department personnel are often the first to arrive at the site of an overdose and start administering emergency medical care. Randolph Firefighters are also

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146 Audrey J. Weiss, *et al.*, *Patient Residence Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014*, HEALTHCARE COST AND UTILIZATION PROJECT (Jul. 25, 2017), https://hcup-us.ahrq.gov/reports/statbriefs/sb226-Patient-Residence-Opioid-Hospital-Stays-ED-Visits-by-State.jsp.

EMTs. Generally, Police Department personnel arrive next. The EMTs generally administer emergency medical services and transport the patient to the hospital.

491. Each call for a drug-related overdose puts an enormous strain and burden on the Town of Randolph. Every time such a call is received by the Town's emergency 911 system, dispatchers must communicate with Town Police, Town Firefighters staffing Firefighting Vehicles and Town Firefighters/EMTs staffing Town Ambulances. Individual Firefighter/EMTs, police officers and/or other firefighters then respond and go out to the scene and investigate the reason for the call. By the time the first responders from the various departments arrive on the scene several Town employees have been assigned to just one call.

492. Providing this emergency medical care is costly, but necessary to combat the health crisis created by Defendants.

Law Enforcement Costs

493. As a result of the opioid epidemic created by Defendants, and the resulting drug overdoses, hospitalizations, and crime, the Town of Randolph has been required to spend and/or allocate additional resources in order combat this epidemic.

494. The opioid epidemic continues to cause a significant drain on Town resources. For example, any time an individual is arrested for opioid- and/or drug-related crimes, the Town bears the cost of housing and caring for the prisoner until that person can be transferred to another facility or is released. Relatedly, each time a call comes in for an opioid overdose, the Randolph Police Department responds, often sending multiple officers to the scene to investigate. Additionally, overtime alone for combating drug-related crime represents a massive cost to the Town.

495. The prosecution and incarceration costs associated with drug-related crimes are substantial and continuing.

496. The Randolph Police Department also provides a kiosk for Prescription Drug Take Backs and the Town participates in a Town-Wide Hazardous Waste Take-Back Day event, where Hazardous Materials, including prescription drugs, are collected by the Town. This requires various Town personnel to manage the kiosk program and the prescription drug return, on a regular basis and particularly on the Hazardous Waste Take-Back Day. The confiscated prescription drugs must then be disposed of.

Diversion Costs

497. The Town of Randolph's employees have been forced to divert time and resources to fight the opioid epidemic created by Defendants that it would otherwise devote to other issues and/or programs. These lost productivity costs can be directly attributed the opioid epidemic.

498. In addition, in order to facilitate the Hazardous Waste Take-Back Day event described above, Randolph uses Town facilities and administrative resources that would otherwise be devoted to other initiatives and programs.

499. Similarly, Town employees, including those from the Randolph Police Department and Department of Public Works, are responding to more and more calls relating to used needles and other discarded items that need to be safely collected and discarded.

500. The Randolph Intergenerational Community Center and the Randolph Turner Free Public Library now must devote time and resources to respond to various drug-related crisis (*i.e.*, suspected drug use in bathrooms and other parts of facilities, increased vagrancy, safety precautions, etc.).

501. The Randolph Department of Public Works has incurred costs for additional monitoring and upkeep of parks and other conservation and recreational spaces in Town.

502. Relatedly, the increase in opioid-addicted populations has caused a related increase in debris and needles, which must be cleaned by the Town and policed by the Randolph Police Department.

503. Furthermore, the Town of Randolph sends personnel (particularly the respective department heads) to attend various conferences, speeches, and seminars concerning the education and training of their employees and subordinates on how to respond to crisis scenarios.

Community Outreach Expenses

504. The Town of Randolph provides various programs and education to the community it serves, particularly with respect to drug addiction and treatment. Moreover, Randolph collaborates on several initiatives geared towards rectifying the damage caused by Defendants' conduct.

505. The Randolph Substance Abuse Prevention Coalition offers Randolph residents the opportunity to participate in educational events as well as providing Narcan training.

Child Care-Related Costs

506. There are also social costs borne by the Town of Randolph that are associated with an increase in the number of addicted persons created by prescription opioids. For example, interventions by Child Protective Services increase and become more acute for families where one or more of the adults are addicted. Notably, expenditures related to child abuse have steadily increased over the last decade, which is in line with the increase in opioid addictions in Massachusetts.

507. According to data from the Massachusetts Department of Children and Families (the "DCF") – the state's child protection agency – "substance abuse is the No. 1 factor in child

abuse and neglect cases in Massachusetts" as of 2016.[147] Approximately 30% of the DCF's caseload stemmed from substance abuse, which outstripped the next two main causes of child maltreatment: domestic violence (21%) and mental health (18%).[148] Petitions to remove children from their homes rose from 2,460 to 3,855 between 2012 and 2016 (a 57% increase).[149] Concurrently, reports of babies born with opioids in their systems rose 11% from 2015 to 2017, according to DCF figures. As reported by the *Boston Globe*:

> The[se] increases have coincided with the spread of the opioid epidemic. As a result, said Maria Mossaides, head of the state's Office of the Child Advocate, the reasons for removing children from their parents' homes have changed dramatically. "You're seeing a huge increase in allegations of neglect or abuse with respect to parents who are users of drugs," she said.[150]

508. Notably, Massachusetts hospitals are required to file a complaint with the Commonwealth when a baby is born exposed to drugs, even if a mother is prescribed the drugs legally. DCF then decides whether or not the child is placed in foster care.

509. From March 2014 to February 2016, DCF responded to 4,788 cases of children born exposed to drugs. More than 700 of those babies were placed in state custody.[151]

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147 Matt Stout, *Substance Abuse Cited as No. 1 Reason for DCF Cases*, BOSTON HERALD (Oct. 11, 2016), https://www.bostonherald.com/2016/10/11/substance-abuse-cited-as-no-1-reason-for-dcf-cases.

148 *Id.*

149 Brian MacQuarrie, *Young Victims of Opioid Crisis Pay High Price*, BOSTON GLOBE, Oct. 7, 2017, https://www.bostonglobe.com/metro/2017/10/07/children-are-lesser-known-victims-opioid-crisis/1D4lkN2kmEzeApqJ1g3BPI/story.html.

150 *Id.*

151 Deborah Becker, *As Mass. Grapples with Opioid Crisis, More Babies Are Being Born Exposed to Drugs*, WBUR (Mar. 25, 2016), http://www.wbur.org/commonhealth/2016/03/25/massachusetts-neonatal-abstinence-syndrome-mgh.

510. As noted above, NAS diagnoses have increased dramatically in the Commonwealth of Massachusetts. Although much attention has been given to related hospital expenses, there are no published estimates of the costs after discharge. Infants born with opioid dependence are at high risk for subsequent mistreatment and frequently require placement in foster care.[152]

511. Ultimately, safe placement of the infant and monitoring after discharge is a complex and labor-intensive process. One recent study took on the task of quantifying the statewide burden of the opioid-related NAS problem by estimating the labor costs of caring for NAS infants within DCF.[153] The study noted "a startling increase in the time spent by area social workers on this single issue."[154]

512. The growing burden of this problem accounts for substantial expenditure of social service resources. Statewide, it is estimated that it accounted for a monthly average of about 10,650 hours in 2013. In the most affected area offices, this single issue occupied the equivalent of about 800 monthly hours. The study further estimated that, in the 2013, this problem consumed around 4.3 million dollars in labor costs alone. To put this into perspective, the total budget for case managers and social workers for the same year was $170.6 million, meaning that these estimates indicate that about 2.5% of the total state budget for personnel was spent on this single problem.

513. When a child is placed in foster care due to an opioid-addicted parent's inability to care for that child, the Town of Randolph provides support to the child through the schools.

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152 França, *et al.*, *supra* n.141.

153 *Id.*

154 *Id.*

514. The strain on Randolph's budget will continue for the foreseeable future and is likely to increase. Addiction is a brain illness that may be brought into remission, but there is no known cure for that devastating disease. It is also known to be a disease where relapses are common.[155] Accordingly, even if the epidemic were stopped in its tracks right now, the damages to Randolph will continue until the health crisis is abated, which will likely take years, if not decades.

* * *

515. Virtually every department within Randolph has been impacted, and forced to incur additional expenses year-after-year to try to provide education, opposition and/or mitigation to the devastating impacts of the opioid epidemic to Randolph residents.

516. By virtue of the deceptive and fraudulent marketing campaign of the Manufacturer Defendants and Individual Defendants, and the failure of the Distributor Defendants to take reasonable care to control the flow of dangerous opioids into the Town, Randolph has incurred expenditures which, on information and belief, are in the tens of millions of dollars and will continue to incur those and even greater expenditures in the foreseeable future as the man-made epidemic continues to unfold.

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155 Thomas R. Kosten & Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 SCI. & PRACT. PERSP. 13 (2002), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054/.

V. CAUSES OF ACTION

COUNT ONE

Public Nuisance
(Against All Defendants)

517. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

518. This claim is brought by the Town of Randolph against all Defendants, individually and acting through their employees and agents and in concert with each other, because each Defendant has intentionally, recklessly, or negligently engaged in conduct that injuriously affected rights common to the general public, specifically the rights of the people of Randolph to public health, public safety, public peace, public comfort, public convenience, and public welfare, without unreasonable interference. *See* RESTATEMENT SECOND, TORTS §821B.

519. Defendants' unlawful marketing, sale, and distribution of opioid prescriptions have created a public nuisance that constitutes a significant, unreasonable interference with these common rights, and have damaged the public generally and whole community. In addition, this interference is continuing in nature and has produced a long-lasting effect.

520. Each Manufacturer Defendant has, and continues to, intentionally, recklessly, and negligently market their opioid products through materially false and misleading statements to physicians, pharmacists, insurers, and members of the general public that misrepresented the characteristics and safety of opioids and resulted in widespread inappropriate use of these highly addictive and dangerous pharmaceuticals. By acting in such a negligent and reckless manner, each Manufacturer Defendant injuriously affected the public health, safety and morals of the community. Moreover, each Manufacturer Defendant had knowledge of the likely and foreseeable harm to the Town and residents of Randolph proximately caused by its unlawful conduct.

521. Each Distributor Defendant has, and continues to, widely disseminate the Manufacturer Defendants' dangerous opioid products in the Town of Randolph, in breach of state law and in a negligent and reckless manner that injuriously affects the public health, safety, and morals of the community. Moreover, each Distributor Defendant had knowledge of the likely and foreseeable harm to the Town and residents of Randolph. Through their promotion, marketing, and distribution of opioids for profit, the Defendants created a public nuisance in the Town proximately caused by their unlawful conduct.

522. Individual Defendant Kapoor was the mastermind behind Insys's blatant, wanton, and willful misrepresentations and unlawful marketing schemes to sell its fentanyl product, Subsys, regardless of the dangers to unsuspecting members of the public within the Town of Randolph. Moreover, he had knowledge of the likely and foreseeable harm to the Town and residents of Randolph proximately caused by his unlawful conduct.

523. As members of the Purdue board of directors, the Sackler Family Defendants caused that company to blatantly, wantonly, and willfully misrepresent, and to unlawfully market and sell its opioid products regardless of the dangers to unsuspecting members of the public within the Town of Randolph, and to the Town of Randolph itself. Moreover, the Sackler Family Defendants had knowledge of the likely and foreseeable harm to the Town and residents of Randolph proximately caused by their unlawful conduct.

524. Defendants knew that opioid prescription drugs are dangerous because these drugs are highly regulated substances under federal and state law due to their addictive qualities and potential for abuse. Defendants' actions created, fueled, and expanded the overuse, misuse, and abuse of opioids, drugs that are specifically codified as constituting severely harmful substances. As such, Defendants created an intentional nuisance.

525. Each Defendant's conduct was unlawful, intentional, and reckless and has resulted in significant and unreasonable interference with the public health, safety, peace, and welfare of Randolph's residents. As such, each Defendant's conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety, and welfare of the Town's residents. The public nuisance created by Defendants' actions is substantial, unreasonable, and continuing and has harmed the entire community in ways that include, but is not limited to, the following:

(a) the high rate of opioid use leads to increased opioid addiction, overdoses, both fatal and otherwise, and an increased number of Randolph residents who are unable to care for themselves or their families due to their addiction;

(b) even residents who are not addicted are affected by the public nuisance Defendants created. The family members of those who became addicted will endure financial and emotional burdens of striving to get help for their loved ones as they grapple with a disease that is not curable and has a formidable relapse rate, or worse have sustained the pain of having a loved one die because of the greed of Defendants;

(c) even residents who are not family members of any addicted person are affected in their use and enjoyment of public areas, such as parks and recreation areas offered by the Town, due to the increased danger of crime posed by an increased population of addicted individuals;

(d) employers have lost the quantifiable value of productive and healthy workers; and

(e) the diversion of Town resources to address the public nuisance of the opioid epidemic has taxed the medical, public health, law enforcement, courts, incarceration systems, and schools of the Town and strained Randolph's financial resources.

526. The Town of Randolph has a clearly ascertainable right and is the appropriate party to require Defendants to abate conduct that perpetuates this public nuisance.

527. The Town of Randolph seeks all legal and equitable relief permitted by law.

COUNT TWO

Common Law Fraud
(Against All Defendants)

528. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

529. Manufacturer and Individual Defendants had knowledge of the material facts that prescription opioids are addictive and that using them for the treatment of chronic pain carries a high risk of addiction and its attendant problems, including overdose, death, or a permanently damaged brain function in affected individuals.

530. Notwithstanding the knowledge described above, all Manufacturer and Individual Defendants falsely represented, or omitted and/or knowingly concealed information rendering the statements false, that prescription opioids are relatively safe for the management of chronic pain.

531. All Manufacturer and Individual Defendants made those false representations to physicians, patients, hospitals, and the communities of America at large, including Plaintiff Town of Randolph.

532. All Manufacturer and Individual Defendants made those false statements to induce large numbers of persons, physicians, patients, and others within the Town of Randolph, as well as the Plaintiff itself, to purchase opioid prescriptions as a form of pain relief.

533. In huge numbers, physicians, physician assistants, nurse practitioners, and hospital staff did indeed prescribe vast quantities of the opioids sold by Manufacturer and Individual Defendants, and large numbers of persons in the Randolph community did indeed take such pills

for chronic pain relief in reliance on the false representations made by the Manufacturer and Individual Defendants.

534. Distributor Defendants knew the material fact that they had a statutory duty under both Massachusetts law and federal law, as well as a common law duty, to protect the public health by monitoring and controlling the amount of prescription opioids that was allowed to enter the Randolph area. They knew they were not discharging that responsibility, failed to alert the DEA and state authorities about "suspicious sales" of drugs, and failed to halt the suspicious sales of drugs throughout the United States, including to the Town of Randolph.

535. The Town of Randolph did, in fact, rely on Distributor Defendants' knowingly false statements and thereby did not become aware, until it was too late, that their community had become flooded with an exorbitant, excessive quantity of opioids.

536. Conduct of all Defendants was willful, wanton, malicious, and directed at the public generally.

537. As a direct and foreseeable consequence of the Defendants' fraudulent acts, Plaintiff has been damaged as alleged herein.

COUNT THREE

Negligent Misrepresentation
(Against All Defendants)

538. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

539. Each Defendant had, and continues to have, an obligation to exercise reasonable care in manufacturing, marketing, selling, and distributing its products to the Commonwealth of Massachusetts, the Town of Randolph, and its surrounding area. Each Defendant breached that duty with the foreseeable devastating consequences to the Town. The injury and harm to the Town was proximately and substantially caused by Defendants' negligent misrepresentation.

540. All Defendants knew they were manufacturing, selling, and/or distributing dangerous drugs, which are designated as Schedule II or III controlled substances due to their addictive and dangerous qualities.

541. Reasonably prudent manufacturers of pharmaceutical products would know that aggressive marketing of highly addictive opioids for long-term chronic pain was likely to cause large numbers of patients to become addicted to their opioid prescriptions, foreseeably causing such patients to need more frequent and higher levels of the opioids for pain relief, and foreseeably turning to the use of street drugs, such as heroin, and fentanyl, which are almost indistinguishable from opioids, both chemically and in the effect on the human brain.

542. Reasonably prudent distributors of pharmaceutical products would anticipate that distribution of such dangerous prescription opioids, without monitoring for, reporting, or halting suspicious sales would wreak havoc on communities, such as the Town of Randolph, which would be inundated with opioids, imposing excessive burdens on the Town to try to contain the problem. The purpose for the closed system of opioid distribution, of which all Defendants were familiar,

was precisely to control the excessive flow of dangerous substances, such as opioids, into communities, such as was experienced, and continues to be experienced, by the Town.

543. Despite this knowledge of grave foreseeable harm from marketing opioids for long-term treatment of chronic pain, without warning of the serious risks of addiction, Manufacturer and Individual Defendants made false and misleading statements and omitted material information, which made the representations false to physicians, nurse practitioners, payors, patients, the public, and the Town, regarding the risk of addiction from long-term use of opioids.

544. Despite this knowledge of grave foreseeable harm to the Town of Randolph from distributing vast quantities of opioids without regard to whether or not the sales were suspicious, and without disclosing the material fact that they were acting in violation of laws and regulations requiring that they maintain a system to prevent suspicious sales, the Distributor Defendants breached their duty to distribute the opioids in a fair and reasonable manner.

545. But for Defendants' material factual omissions and misrepresentations, Defendants would not have been able to sell the dangerous quantity of opioids into the Town of Randolph and its surrounding areas. As a direct and foreseeable consequence of the Manufacturer and Individual Defendants' negligent misrepresentations, Plaintiff has been damaged as alleged herein.

COUNT FOUR

Negligence
(Against All Defendants)

546. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

547. All Defendants have a duty to exercise reasonable care in the distribution of opioids.

548. Violations of statutes and regulations are evidence of negligence, where the harm sustained by Defendants' statutory or regulatory violations is the type sought to be prevented and the violations proximately caused.

549. All Defendants' negligent conduct involved violations of Massachusetts statutory law, and the harm caused by the negligence was the type sought to be prevented by the statute.

550. Mass. Gen. Laws ch. 266, §91 states that it is unlawful to use false advertising to "increase the consumption of or demand" for any product or service, including drugs. False advertising constitutes any advertisement that is "untrue, deceptive, or misleading."

551. Mass. Gen. Laws ch. 226, §76 makes conduct that constitutes "gross fraud or cheat at common law" a felony. All frauds perpetrated against the general public, and against which ordinary prudence was no safeguard, constitutes the common law of "cheat."

552. The fraud against the general public and perpetrated by the Manufacturer and Individual Defendants against patients, payors, physicians, families of harmed persons, and the general community in Randolph, by perpetrating the myth that opioids were a safe and effective therapy for long-term chronic pain (so as to increase consumption of their product), constitutes the common law of cheat, since it harmed the general public, and the fraud was so pervasive that prudence was not an available safeguard. As such, the Manufacturer Defendants' violation of this criminal statute is the type sought to be prevented by Mass. Gen. Laws ch. 226, §76, and their violations proximately caused Plaintiff harm.

553. The Manufacturer Defendants' violations of Mass. Gen. Laws ch. 266, §91 and ch. 226, §76, by disseminating false advertisements of their opioid drugs, constitute negligence under Massachusetts law.

554. The Distributor Defendants' conduct relating to the wholesale distribution of controlled substances is governed by Mass. Gen. Laws ch. 94C, §12(a), 105 CMR 700.006(A), 247 CMR 7.04(9)(a) and (b), and the Federal Controlled Substances Act, 21 U.S.C. §801, *et seq.* ("FCSA").

555. Mass. Gen. Laws ch. 94C, §12(a), 105 CMR 700.006(A), and the FCSA all create statutory standards that require prescription drug distributors to maintain and monitor a closed chain of distribution and detect, report, inspect, and halt suspicious orders, so as to prevent the black market diversion of controlled substances.

556. More specifically, Massachusetts state and regulatory law requires that the Distributer Defendants know the average number of their opioid prescriptions filled daily, how the percentage of controlled substances compares to a customer's overall purchases, how the pharmacist fulfills its responsibility to ensure that prescriptions are being fulfilled for legitimate medical purposes, and the identities of "pill mill" outlets that are the pharmacists' most frequent prescribers.

557. Mass. Gen. Laws ch. 226, §76 makes conduct that constitutes "gross fraud or cheat at common law" a felony. All prescribed frauds perpetrated against the general public and against which ordinary prudence was no safeguard constitutes the common law of "cheat."

558. The fraud against the general public perpetrated by the Distributor Defendants against the Town of Randolph and its general community, by allowing the Town to become awash in opioid prescription drugs that far exceeded any legitimate medical need, solely for their wrongful profit, constitutes the common law of cheat, since it harmed the general public and ordinary prudence by the Town would not have been able to safeguard the Plaintiff until the harm had already occurred. Since the Distributor Defendants' violation of this criminal statute is the

type sought to be prevented by Mass. Gen. Laws ch. 226, §76, Distributor Defendants' violations proximately caused Plaintiff's harm.

559. The Distributor Defendants' violations of the statutory and regulatory standards set forth in the Mass. Gen. Laws ch. 94C, §12(a), 105 CMR 700.006(A), and the FCSA constitute negligence under Massachusetts law.

560. Mass. Gen. Laws ch. 226, §111A makes it a crime for any person to knowingly submit claims under an insurance policy with the "intent to injure, defraud, or deceive" any insurer.

561. Among the many crimes committed by Defendant Insys, and its control persons named as numerous former Insys executives and managers regarding the unlawful manner in which Insys sold and marketed its powerful opioid, Subsys, throughout the Town of Randolph and surrounding areas, was the crime of insurance fraud by setting up a standard operating procedure to mislead insurance companies that Subsys was being prescribed for cancer patients, when Insys and Individual Defendant Kapoor knew that Subsys was, in fact, being prescribed for patients for whom it was unsafe and medically contra-indicated who were not cancer patients.

562. Defendant Insys's and Individual Defendant Kapoor's violations of the statutory standards set forth in Massachusetts state and federal law, including, but not limited to, Mass. Gen. Laws ch. 226, §111A, constitute negligence under Massachusetts law.

563. Defendant Insys's and Individual Defendant Kapoor's violations of various criminal laws were, and are, a substantial factor in the injuries and damages sustained by Plaintiff.

564. As a direct and proximate result of the lack of reasonable care by Defendants in conducting their business of distributing pharmaceutical products at the wholesale level, Plaintiff was flooded with opioid prescriptions well beyond any legitimate medical need.

565. As a direct and foreseeable consequence of Defendants' negligent conduct, Plaintiff has been damaged as alleged herein. Defendants' violations of the state and federal statutes, and public safety regulations cited herein were and are a substantial factor in the injuries and damages sustained by Plaintiff.

566. It was foreseeable that Defendants' breach of statutory and regulatory laws described herein would result in the damages sustained.

567. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence.

COUNT FIVE

Violations of Mass. Gen. Laws ch. 93A, *Section 11*
(Against All Defendants)

568. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

569. Defendants engaged in unfair and deceptive acts and practices in violation of Mass. Gen. Laws ch. 93A. The actions and transactions constituting the unfair or deceptive acts and practices of each Defendant occurred primarily and substantially within the Commonwealth of Massachusetts.

570. Manufacturer Defendants made or, through their control of, and by aiding and abetting, third parties, caused to be made, untrue, false, misleading, and deceptive statements of material fact, or made, or caused to be made, statements that omitted or concealed material facts, rendering the statements misleading, to prescribers, consumers, payors, and Plaintiff, in connection with Defendants' marketing, promotion, sale, and use of prescription opioids. These untrue, false, misleading, and deceptive statements of material fact made to the Town of Randolph included, but were not limited to, the following:

(a) misstatements relating to the addictive nature of opioids;

(b) misstatements relating to the risk of overdose, death, and irreversible damage to the brain;

(c) misstatements relating to the titration schedules of opioids;

(d) misstatements to the treating physicians;

(e) Manufacturer Defendants' failure to disclose that opioids are highly addictive and should not be used for long-term use for chronic pain;

(f) Distributor Defendants' failure to disclose to federal and state authorities that there were suspicious sales of prescription opioids being made to the Town of Randolph and failure to stop them;

(g) Manufacturer Defendants' false claims to the medical community, in general, residents of Randolph, and Randolph relating to the risks and safety of the use of opioids for the treatment of chronic pain;

(h) misstatements relating to and the use of unfair and deceptive practices in connection with KOLs' creation of false fronts and infiltration of medical societies to perpetuate the Defendants' false message to physicians and peddle their products to masses of persons for whom they were dangerous and caused death or permanent brain damage;

(i) misstatements relating to the viability, risks, benefits, and superiority of alternative treatments;

(j) Purdue's and Endo's false claims that abuse-deterrent opioids reduce tampering and abuse; and

(k) Purdue's false claims that OxyContin provides a full 12 hours of pain relief.

571. Manufacturer Defendants knew, or should have known, at the time of making or disseminating the false statements and material omissions, that they were untrue, false, misleading, and deceptive, and therefore, likely to deceive the public, prescribers, payors, and Town of Randolph, of the risks, benefits, and superiority of opioids.

572. Manufacturer Defendants directly engaged in false, untrue, and misleading marketing and disseminated the false, untrue, and misleading marketing themselves and through third parties whom they aided and abetted. Manufacturer Defendants made these statements with the intent that the Town of Randolph and its residents would rely on them, and it was reasonably foreseeable to the Manufacturer Defendants that such reliance would result in the use of opioid prescriptions by persons in quantities and for durations that would cause death or severe harm to users and harm to the Town. Manufacturer Defendants intended to deceive the physicians who prescribed opioids to the residents of Randolph and payors, who purchased, or covered the purchase of, opioids for chronic pain.

573. The Town of Randolph and its residents did rely on Defendants' false, misleading, and unconscionable statements, and the Town has sustained ascertainable losses as a direct and proximate result.

COUNT SIX

Unjust Enrichment
(Against all Defendants)

574. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

575. All Defendants received and accepted a material benefit from Randolph's expenditure of funds for the purchase of opioid prescriptions for its insured employees and retirees under the Town's workers' compensation and medical benefits plans. This material benefit and

profit garnered by Defendants from opioid prescriptions purchased and paid for by Plaintiff and its residents was the expected and intended result of Defendants' conscious wrongdoing. Defendants accepted the payment without protest, retained and benefited from those payments, and have refused to voluntarily disgorge their unjust enrichment.

576. At the time Randolph made these expenditures, it did so in reliance and under the belief that it was provided with all the necessary and accurate information regarding the risks and benefits of opioid use. The Town relied on the truthfulness and accuracy of Defendants' misrepresentations and omissions to its detriment because it agreed to confer a benefit on Defendants, which the Town would not have done, but for the wrongful conduct of Defendants.

577. Retention of these benefits by each of the Defendants would be unjust.

578. Additionally, it would be inequitable to allow the Town of Randolph to continue to bear the cost of expenditures it was forced to make to try to support the health and safety of its residents, in the face of the opioid epidemic in its community created by the Defendants, without shifting the full amount of those expenditures from the Town to the Defendants.

579. Defendants must disgorge their unlawfully and unjustly acquired profits and benefits resulting from their unlawful conduct and must provide full restitution to Plaintiff.

COUNT SEVEN

Civil Conspiracy
(Against all Defendants)

580. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

581. As set forth herein, Defendants engaged in a concerted action and civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution, and/or diversion of opioids into Massachusetts and Plaintiff's community, all in furtherance of

WHEREFORE, Plaintiff seeks all legal and equitable relief, as allowed by law, except as expressly disavowed herein, including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Town of Randolph demands judgment against each Defendant, jointly and severally, in favor of the Plaintiff, as follows:

A. Under Count 1, awarding damages for Defendants' tortious conduct and requiring Defendants to pay for all costs to abate the public nuisance;

B. Under Counts 2-4 and 7, awarding damages for Defendants' tortious conduct;

C. Under Count 5, awarding actual damages, treble damages, and attorneys' fees and costs for Defendants' violations of Mass Gen. Laws ch. 93A.

D. Under Count 6, ordering all Defendants to disgorge all wrongfully retained enrichment for the benefit of Plaintiff;

E. Enjoining Defendants and requiring them to notify their employees, officers, directors, agents, successors, assignees, predecessors, parent or controlling entities, subsidiaries, and all heirs, beneficiaries, and assigns of Individual Defendant, and any other person acting in concert with any of the above from continuing to engage in unfair or deceptive practices or continuation of their fraud, or negligence, in violation of law and ordering all temporary, preliminary, or permanent injunctive relief;

F. Ordering injunctive and equitable relief, as deemed proper by the Court;

G. Awarding pre-judgment and post-judgment interest; and

H. For all other relief deemed to be appropriate by the Court.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

Dated: March 22, 2019

THE TOWN OF RANDOLPH
By its attorneys,

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Beth A. Kaswan (BBO #260680)
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CIVIL ACTION COVER SHEET

DOCKET NUMBER

Trial Court of Massachusetts
The Superior Court

PLAINTIFF(S): TOWN OF RANDOLPH	COUNTY: Norfolk
ADDRESS: 41 SOUTH MAIN STREET, RANDOLPH, MA 02368	DEFENDANT(S): PURDUE PHARMA L.P. D/B/A PURDUE PHARMA (DELAWARE) LIMITED PARTNERSHIP, ET AL. (SEE ATTACHED LIST OF DEFENDANTS)
ATTORNEY: JUDITH S. SCOLNICK	
ADDRESS: SCOTT+SCOTT ATTORNEYS AT LAW LLP	ADDRESS:
230 PARK AVENUE, 17TH FLOOR, NEW YORK, NY 10169	
(212) 223-6444	
BBO: 449100	

TYPE OF ACTION AND TRACK DESIGNATION (see reverse side)

CODE NO.	TYPE OF ACTION (specify)	TRACK	HAS A JURY CLAIM BEEN MADE?
B99	PUBLIC NUISANCE	F	[x] YES [ ] NO

*If "Other" please describe:

Is there a claim under G.L. c. 93A? [x] YES [ ] NO

Is this a class action under Mass. R. Civ. P. 23? [ ] YES [x] NO

STATEMENT OF DAMAGES PURSUANT TO G.L. c. 212, § 3A

The following is a full, itemized and detailed statement of the facts on which the undersigned plaintiff or plaintiff's counsel relies to determine money damages. For this form, disregard double or treble damage claims; indicate single damages only.

TORT CLAIMS
(attach additional sheets as necessary)

A. Documented medical expenses to date:
1. Total hospital expenses ..... $
2. Total doctor expenses ..... $
3. Total chiropractic expenses ..... $
4. Total physical therapy expenses ..... $
5. Total other expenses (describe below) ..... $
Subtotal (A): $

B. Documented lost wages and compensation to date ..... $
C. Documented property damages to date ..... $
D. Reasonably anticipated future medical and hospital expenses ..... $
E. Reasonably anticipated lost wages ..... $
F. Other documented items of damages (describe below) $10,000,000

G. Briefly describe plaintiff's injury, including the nature and extent of injury:
MUNICIPAL EXPENDITURES AND OTHER DAMAGES RESULTING FROM OPIOID EPIDEMIC

TOTAL (A-F): $10,000,000

CONTRACT CLAIMS
(attach additional sheets as necessary)

[ ] This action includes a claim involving collection of a debt incurred pursuant to a revolving credit agreement. Mass. R. Civ. P. 8.1(a).
Provide a detailed description of claim(s):

TOTAL: $

Signature of Attorney/ Unrepresented Plaintiff: X Judith S. Scolnick **Date: 3/26/2019**

RELATED ACTIONS: Please provide the case number, case name, and county of any related actions pending in the Superior Court.

CERTIFICATION PURSUANT TO SJC RULE 1:18

I hereby certify that I have complied with requirements of Rule 5 of the Supreme Judicial Court Uniform Rules on Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected dispute resolution services and discuss with them the advantages and disadvantages of the various methods of dispute resolution.

Signature of Attorney of Record: X Judith S. Scolnick **Date: 3/26/2019**

LIST OF DEFENDANTS

Town of Randolph v. Purdue Pharma L.P. d/b/a Purdue Pharma (Delaware) Limited Partnership, et al.

PURDUE PHARMA L.P. d/b/a PURDUE PHARMA (DELAWARE) LIMITED PARTNERSHIP;

PURDUE PHARMA INC.;

THE PURDUE FREDERICK COMPANY, INC.;

TEVA PHARMACEUTICALS USA, INC.;

CEPHALON, INC.;

COLLEGIUM PHARMACEUTICAL, INC.;

JOHNSON & JOHNSON;

JANSSEN PHARMACEUTICALS, INC.;

ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.;

ENDO HEALTH SOLUTIONS INC.;

ENDO PHARMACEUTICALS, INC.;

ALLERGAN PLC f/k/a ACTAVIS PLC;

ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.;

WATSON LABORATORIES, INC.;

ACTAVIS LLC;

ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.;

MALLINCKRODT PLC;

MALLINCKRODT LLC;

INSYS THERAPEUTICS, INC.;

MCKESSON CORPORATION;

CARDINAL HEALTH, INC.;

AMERISOURCE BERGEN DRUG CORPORATION;

CVS HEALTH CORPORATION;

LIST OF DEFENDANTS

Town of Randolph v. Purdue Pharma L.P. d/b/a Purdue Pharma (Delaware) Limited Partnership, et al.

CVS PHARMACY, INC.;

RITE AID CORPORATION;

RITE AID OF MASSACHUSETTS, INC.;

WALGREENS BOOTS ALLIANCE, INC.;

WALGREEN EASTERN CO., INC.;

WALGREENS MAIL SERVICE, L.L.C.;

WALGREENS OF MASSACHUSETTS, L.L.C.;

WALGREENS SPECIALTY PHARMACY, L.L.C.;

WALMART, INC.;

WAL-MART.COM USA, L.L.C.;

WAL-MART STORES EAST, INC.;

WAL-MART STORES EAST, L.P.;

JOHN KAPOOR;

RICHARD SACKLER;

THERESA SACKLER;

KATHE SACKLER;

JONATHAN SACKLER;

MORTIMER D.A. SACKLER;

BEVERLY SACKLER;

DAVID SACKLER; and

ILENE SACKLER LEFCOURT